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In The
Supreme Court of the United States

WARNER-LAMBERT COMPANY and PFIZER INC.,

Petitioners,

v.

MARY ROSE WAKEFIELD, INDIVIDUALLY, AS PERSONAL REPRESENTATIVE, TRUSTEE, EXECUTOR OF THE ESTATE OF MICHAEL HOLMES WAKEFIELD AND MARY LOUISE WAKEFIELD,

Respondent.

On Petition For Writ Of Certiorari To The Oklahoma Court Of Civil Appeals

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the $10 million punitive damage award was excessive and arbitrary, in violation of the Due Process clause of the Fourteenth Amendment, because it was calculated from world-wide gross sales of an FDA-approved prescription drug, in conflict with *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003), and *BMW of North America v. Gore*, 517 U.S. 559, 573 (1996).

2. Whether the $10 million punitive damage award, nearly seven times the $1.55 million compensatory damage award, was grossly excessive under the standard in *State Farm*, 538 U.S. at 425, that "an award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety," and that where, as here, "compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee."

RULE 29.6 STATEMENT

Petitioner Warner-Lambert Company is a wholly-owned subsidiary of petitioner Pfizer Inc. Pfizer Inc. has no parent corporation. No publicly held company owns 10% or more of the stock of Pfizer Inc.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Warner-Lambert Company ("Warner-Lambert") and Pfizer Inc. ("Pfizer") respectfully petition for a writ of certiorari to review the judgment of the Oklahoma Court of Civil Appeals in this case, which affirmed a judgment following a jury verdict of $1.55 million compensatory damages and $10 million punitive damages against petitioners.

OPINION BELOW

The unpublished opinion of the Oklahoma Court of Civil Appeals, filed on July 20, 2004, is reprinted in the attached appendix ("App.") at 1-19.

STATEMENT OF JURISDICTION

The Supreme Court of Oklahoma denied petitioners' timely petition for certiorari on November 1, 2004, without opinion. App. 20. Petitioners invoke this Court's jurisdiction under 28 U.S.C. § 1257(a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fourteenth Amendment to the U.S. Constitution, § 1, and the Oklahoma punitive damages statute, 23 OKLA. STAT. § 9.1, are reprinted at App. 22-25.

STATEMENT OF THE CASE

This product liability action arises from the treatment of diabetes with the prescription drug Rezulin, which was manufactured by defendant Warner-Lambert. Rezulin was found to be safe and effective and was approved for sale by the U.S. Food and Drug Administration ("FDA"). The FDA has the statutory responsibility to approve and regulate prescription drugs, and to weigh their risks against the benefits of effective treatment for diseases such as diabetes, which can be life-threatening. *See* 21 U.S.C. § 355(d). After Rezulin was in use for about three years, it was withdrawn from the market when two next-generation drugs of the same type were introduced. Each of these diabetes drugs, like hundreds of other prescription drugs, has a potential for liver damage in some patients, as their FDA-approved warnings state.

As is commonplace in today's tort environment, following the withdrawal of Rezulin thousands of lawsuits were filed. While there were some plaintiffs' verdicts, such as this case, there were also a number of defendants' verdicts as well as numerous dismissals as a matter of law. While Rezulin was in use, the FDA repeatedly found that its benefits for diabetics outweighed its risks; the vast majority of Rezulin patients had no liver side-effects. And in the trial of this case, every treating physician testified to Rezulin's safety and effectiveness.

Despite these facts, the trial court below allowed plaintiffs' counsel to argue that the jury should calculate punitive damages based on the alleged profit on *worldwide* Rezulin sales during the five-week period when Mr. Wakefield was treated with samples of the drug. The court refused instructions, based on principles set forth in *BMW*

of North America v. Gore, 517 U.S. 559, 572-73 (1996), and reiterated in *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003), to limit the jury's focus to Oklahoma transactions. The huge punitive damage verdict that resulted, if allowed to stand, in effect allows one jury in one state court lawsuit to override FDA decisions and to regulate the legality of prescription drug sales nationwide and, indeed, worldwide. Thus, the Oklahoma courts' blatant rejection of this Court's limitations on punitive damages affects national health care policy, raising issues that extend far beyond those decided in *BMW* and *State Farm*.

The FDA-approved product at issue. Rezulin was a breakthrough diabetes medication that controlled blood sugar levels when existing drugs could not. As one senior FDA official told an Advisory Committee before Rezulin was approved: "we do not have effective therapy, drug therapy, for Type II diabetes presently, and we urgently need new therapies for this condition." R.3825, DX-0932 at 16.[1] In January 1997 the FDA approved Rezulin after finding that it was "safe and effective for use" and that its benefits outweighed its risks. R.3789, Tr. 958-59; R.3791, Tr. 1248; R.3792, Tr. 1297, 1320-24, 1330-34. The FDA's Director of the Division of Metabolic and Endocrine Drug Products stated that Rezulin "was shown to have distinct benefits in respect to improved glycemic [blood sugar] control and/or insulin reduction in an impressive percentage of patients who were inadequately controlled with insulin." R.3815, Tr. 2912. Thereafter, the FDA approved Rezulin for two additional uses, following further evaluation of its

[1] "R." refers to the record in the Oklahoma Court of Civil Appeals.

benefits as well as the risk of liver injury associated with the drug. R.3792, Tr. 1337. In March 1999, an FDA advisory committee with a "distinguished panel of experts" considered the actual performance of Rezulin based on millions of uses and adverse event reports that included liver injury in some patients. The FDA committee voted to approve Rezulin for continued use in combination with insulin or sulfonylurea drugs. R.3793, Tr. 1400-01; R.3794, Tr. 1497-98. Rezulin was withdrawn in March 2000 after two second-generation drugs of the same type (Actos and Avandia) were introduced. R.3819, Tr. 3043. Those drugs also have been associated with liver injuries at somewhat lower levels, and their labels recommend regular liver function tests. R.3794, Tr. 1469-70; R.3814, Tr. 2749-50.

Mr. Wakefield. Plaintiff's decedent, Michael Wakefield, had life-threatening diabetes, and was treated with Rezulin for about five weeks beginning in February 1999. R.3797, Tr. 1768-69; R.3798, Tr. 1846-48, 1882. Prior to his Rezulin treatment, Mr. Wakefield had been hospitalized five times for diabetic ketoacidosis, a potentially fatal blood condition. R.3808, Tr. 2259, 2263-65; R.3810, 2274. During his last hospitalization for ketoacidosis on March 8, 1999, he was given an antibiotic, Rocephin, made by a company not involved in this case. R.3798, Tr. 1852-53, 1887; R.3797, Tr. 1771, 1786. He then developed hemolytic anemia (R.3798, Tr. 1856), from which he died on March 15, 1999. ***Every*** treating physician concluded, and a specific blood test confirmed, that Mr. Wakefield's death resulted from hemolytic anemia caused by Rocephin. R.3797, Tr. 1793-95; R.3798, Tr. 1903; R.3804, Tr. 2060-61. The Rocephin product label expressly lists hemolytic anemia as a reported adverse reaction. R.3796, Tr. 1756-57. The treating physicians unanimously concluded that

Mr. Wakefield's death was not caused by Rezulin. R.3797, Tr. 1795; R.3798, Tr. 1903; R.3804, Tr. 2033-34.

It was undisputed that all diabetes drugs have risks, which do not preclude their use in light of the life-threatening nature of the disease. The FDA-approved label in effect when Mr. Wakefield took Rezulin had a black-box warning about possible "idiosyncratic hepatocellular [liver] injury," which could result in "hepatic [liver] failure leading to death or liver transplant." R.3825, DX 7. Mr. Wakefield's prescribing physician, Dr. Simon Levit, testified that he was "very aware that the drug had potential side effects regarding the liver," and knew that he "needed to watch for hepatic dysfunction" and did so. R.3798, Tr. 1844-45, 1867.

Despite the risks, every physician involved in this case who had prescribed Rezulin (except plaintiffs' paid expert, Dr. Julie, who was not a diabetes specialist) testified to its overall safety and effectiveness. None observed any serious liver injury to their patients who took Rezulin. For example, Dr. Levit testified that Rezulin was needed to supplement other treatments because it "had another way of working," and that he "felt the drug had definite usage and definite indications and I wanted to use it." R.3798, Tr. 1882, 1884. Dr. Hanson, Mr. Wakefield's endocrinologist, "found it to be an excellent drug," with "really outstanding" effectiveness, which he prescribed for "hundreds of patients." R.3797, Tr. 1779; R.3798, Tr. 1836. *See also* R.3815, Tr. 2889; R.3817, Tr. 3025, 3034.

Proceedings below. The case went to trial against Warner-Lambert and Pfizer in March 2002 before a jury in the District Court of Tulsa County, Oklahoma. Plaintiff had originally named Dr. Levit as a defendant as a ploy to

defeat removal to a federal court (which would have applied the requirements of *BMW* and *State Farm*); plaintiff voluntarily dismissed him on the first scheduled day of trial. R.2896.

After the first phase of the trial, in which the jury awarded $1.55 million in compensatory damages, the case proceeded to a punitive damages phase. The court denied defendants' request to charge the jury that it may not punish defendant "for any impact its conduct may have had on individuals in other states" (R.3231, Nos. 41; R.3823, Tr. 3393-94), based on *BMW*, 517 U.S. at 572-73 (*State Farm* had not yet been decided). The court also overruled objections that punishment of defendants based on out-of-state conduct is unconstitutional, and that there was inadequate evidence from which the jury could determine punitive damages under 23 OKLA. STAT. § 9.1(C), based on "the increased financial benefit derived by the defendant as a direct result of the conduct causing the injury to the plaintiff and other persons or entities." R.3823, Tr. 3387-90. Instead, the court gave the jury a perfunctory instruction essentially in the words of the Oklahoma statute. *Id.* at 3401-02. The jury was not told by the trial court of any geographic or substantive limitations which they could apply to properly compute financial benefit from the conduct that caused injury to the plaintiff. Nor did the court define who the "other persons or entities" were, for whom financial benefit from harm could be calculated, or the geographic location of such other persons or entities.

Plaintiffs' counsel then asked the jury to award punitive damages based on Warner-Lambert's alleged worldwide profit on Rezulin, which she asserted was $21 million for the five-week period during which Mr. Wakefield was treated

with Rezulin and "$600 million, which is the three-year profit that this company made off this drug." *Id.* at 3410. While the annual gross sales were taken from Warner-Lambert's annual reports, there was no evidence of actual profits. Plaintiff's counsel told the jury that Warner-Lambert's profit on Rezulin was 30% (*id.*), but that was simply what the company intended to "strive" for; there was no proof of the amount of actual profits. R.3806, Tr. 2090. Plaintiff's counsel did not present any evidence that selling Rezulin during this five-week period was illegal, and could not do so given the FDA approval. Nor did plaintiff show that other people in Oklahoma had been injured by the drug. To the contrary, the treating physicians, who were local practitioners, testified to the drug's safety and effectiveness.

Defendants' argument that the punitive damage award is unconstitutional was amply preserved. The trial court overruled defendants' objections that common law, statutory and federal constitutional requirements for punitive damages were not satisfied. R.3823, Tr. 3386-90, 3399-3400. Defendants then raised the constitutional issue in their Motion for Judgment Notwithstanding the Verdict, New Trial, Remittur, and to Correct, Open, Modify or Vacate the Judgment (R.3294-3307), which was overruled on March 10, 2003, without opinion. R.3740-41. Defendants raised the constitutional issue again in their appellate brief (at 26-29) and in their petition for certiorari to the Supreme Court of Oklahoma (at 8-10).

The Oklahoma Court of Civil Appeals affirmed the judgment in its entirety. Specifically, the court endorsed the calculation of punitive damages based on financial benefit measured by profit from "world-wide gross sales." App. 17. The court also accepted plaintiffs' assertion that

there was testimony to support a 30% profit margin when there was no such proof. As discussed below, the court simply failed to address the conflict between the calculation of the punitive damage award and the constitutional requirements for considering out-of-state conduct specified by the Supreme Court in *BMW* and *State Farm*. App. 17-19. Moreover, the gross errors underlying the punitive damage award were part of a larger pattern of error in other aspects of the trial, and the appellate review was so divorced from the controlling case law and the record, as to make the entire proceeding an outrageous miscarriage of justice against two out-of state defendants.

Plaintiff's evidence of causation rested entirely on the testimony of plaintiff's paid expert Dr. Julie, a Maryland physician who offered no testimony about the effect of Rezulin on Oklahoma patients. R.3795, Tr. 1625. Dr. Julie opined that Rezulin caused Mr. Wakefield's hemolytic anemia, but could not cite any study finding that Rezulin can cause hemolytic anemia. *Id.* at 1648-49. Two treating physicians also testified that there was no indication of any liver injury. R.3797, Tr. 1780-83; R.3798, Tr. 1860. Indeed, even at his death Mr. Wakefield's liver was in such good condition that it was transplantable. R.3815, Tr. 2975; R.3819, Tr. 3066. Yet, the Oklahoma Court of Civil Appeals asserted (without citation) that Mr. Wakefield had a liver injury when he was hospitalized. App. 2. Defendants challenged the reliability of Dr. Julie's opinions, but the trial court allowed him to testify without making any findings or applying any legal standard. The court simply "assume[d]," based on the word of plaintiff's counsel, that Dr. Julie "must have some basis for his opinion." R.3780, Tr. 36. The Court of Civil Appeals affirmed, without applying any of the factors in *Daubert v. Merrell Dow*

Pharm., 509 U.S. 579, 592-93 (1993), which Oklahoma has adopted. App. 12.

The trial court denied defendants' request that no jury instruction be given on strict liability or, alternatively, to allow the jury to decide whether Rezulin was unavoidably unsafe under Comment k to the RESTATEMENT (SECOND) OF TORTS, § 402A (1965), particularly in light of its FDA approval (R.3820-22, Tr. 3213-14, 3235-36 3376-78), despite Oklahoma case law stating that under Comment k all prescription drugs are "unavoidably unsafe" and there is no liability if an adequate (non-negligent) warning is given. The trial court also refused instructions distinguishing a condition from a cause, which allowed plaintiff's counsel to argue that if Mr. Wakefield even had nausea as a result of Rezulin, went to the hospital, and died there from Rocephin, defendants should be liable. R.3822, Tr. 3365-66. It is thus apparent that, in contrast to *State Farm*, the case for liability was weak, particularly given the sharp dispute on the medical issues between plaintiffs' paid expert and the treating physicians. A $10 million punitive damage judgment that might have been predicated on nausea as a side-effect to an otherwise effective drug is beyond the pale.

REASONS FOR GRANTING THE WRIT

The Court is called upon here not merely to address the Oklahoma courts' flagrant disobedience of this Court's decisions in *BMW of North America v. Gore*, 517 U.S. 559 (1996), and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003). In addition, for the first time, the Court is asked to consider the extent to which the constitutional

protections in those cases limit a state's power to impose punitive damages in a product liability action against out-of-state defendants when the only basis for calculating punitive damages was worldwide sales of the product, which were authorized in the United States by the FDA and in other countries by their regulatory agencies. The importance of correctly applying constitutional protections in these circumstances is demonstrated by the adverse consequences for health care of enabling one state, through its juries, to effectively regulate the out-of-state sale of drugs which, in the FDA's judgment, have benefits that outweigh their possible side-effects. The impact of such state regulation through jury trials and punitive damage awards can be exacerbated many times over by numerous such lawsuits and punitive damage awards, both against these defendants and in the plethora of product liability actions involving pharmaceutical manufacturers around the country.[2]

In granting certiorari to review the legality of a state libel judgment, the Court observed: "Whether or not a newspaper can survive a succession of such judgments, the pall of fear and timidity imposed upon those who would give voice to public criticism is an atmosphere in which the

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[2] Recent punitive damage awards in drug and medical product liability cases include *Coffey v. Wyeth*, No. E-167334 (Dist. Ct. Jefferson Co. Tex. Apr. 7, 2004) ($900 million punitive damages in Pondimin case); *Arrow Int'l, Inc. v. Sparks*, 98 S.W.3d 48 (Ark. Ct. App. 2003) ($4 million punitive damages in medical device case); *McClain v. Metabolife Int'l, Inc.*, 259 F. Supp. 2d 1225 (N.D. Ala. 2002) ($3.25 million punitive damages in cases involving Metabolife); *Axen v. American Home Prod. Corp.*, 974 P.2d 224 (Or. App. 1999) ($20 million punitive damages in case involving Cordarone); *Lovett v. Wyeth Ayerst*, No. 97-00665 (Dist. Ct. Van Zandt Co. Tex. Aug. 1999) ($20 million punitive damages in Phen-Fen case).

First Amendment freedoms cannot survive." *New York Times Co. v. Sullivan*, 376 U.S. 254, 278 (1964).[3] By a parity of reasoning, development of new drugs by pharmaceutical companies will be threatened by "the pall of fear and timidity" that would be imposed by a succession of punitive damage judgments calculated on the basis of FDA-approved national or worldwide sales of innovative prescription drugs, which have risks but nevertheless save many lives. If the decision below is allowed to stand, the due process protections this Court has imposed on punitive damage awards will be nullified, with adverse consequences for medical progress and health care.

This Court also has stated that: "We are concerned with federal issues and a contention that a state court disregarded a federal constitutional ruling of the Court." *Limbach v. Hooven & Allison Co.*, 466 U.S. 353, 362 (1984). Following that principle, the Court has repeatedly

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[3] The Court also noted that: "The Times states that four other libel suits based on the advertisement have been filed against it," that there was another large verdict, and that damages sought in three other cases total $2 million." *See id.* at n.18. In addition to thousands of suits filed against these defendants regarding Rezulin, *see, e.g., In re Rezulin Prod. Liab. Litig.*, 210 F.R.D. 61 (S.D.N.Y. 2002), there are numerous multi-district litigation proceedings involving pharmaceuticals against other manufacturers, including *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prod. Liab. Lit.*, MDL 1203 (E.D. Pa.); *In re Rezulin Prod. Liab. Lit.*, MDL 1348 (S.D.N.Y); *In re Propulsid Prod. Liab. Lit.*, MDL 1355 (E.D. La.); *In re Baycol Prod. Liab. Lit.*, MDL 1431 (D. Minn.); *In re Serzone Prod. Liab. Lit.*, MDL 1477 (S.D. W. Va.); *In re Meridia Prod. Liab. Lit.*, MDL 1481 (N.D. Ohio); *In re Paxil Prod. Liab. Lit.*, MDL 1574 (C.D. Cal.); *In re Zyprexa Prod. Liab. Lit.*, MDL 1596 (E.D.N.Y.); *In re Accutane Prod. Liab. Lit.*, MDL 1626 (M.D. Fla.), and many un-removable state court actions.

granted certiorari in cases where, as here, a state court decision conflicts with Supreme Court case law.[4]

The Oklahoma Court of Civil Appeals failed to remedy the constitutional infirmities in the trial court's punitive damage award and related proceedings. Far from applying "[e]xacting appellate review" to ensure that "an award of punitive damages is based upon an 'application of law, rather than a decisionmaker's caprice,'" as required by this Court (*State Farm*, 538 U.S. at 418), the Court of Civil Appeals simply ignored the constitutional issues and standards set forth in *State Farm* and *BMW*, which preclude punitive damage calculations based on out-of-state or nationwide transactions, whether the court awarding the damages determines that such conduct was legal or illegal. The result was an egregious conflict with this Court's rulings. Summary reversal under Supreme Court Rule 16(1) is therefore warranted.

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[4] *See, e.g., Lilly v. Virginia*, 527 U.S. 116, 123 (1999) ("Our concern that this decision represented a significant departure from our Confrontation Clause jurisprudence prompted us to grant certiorari"); *Oregon v. Mathiason*, 429 U.S. 492, 492-93 (1977) (certiorari granted and judgment reversed because lower court "read *Miranda* too broadly"); *City of Pittsburgh v. Alco Parking Corp.*, 417 U.S. 369, 371-72 (1974) ("Because the decision [of the Pennsylvania Supreme Court] appeared to be in conflict with the applicable decisions of this Court, we granted certiorari"); *Willam E. Arnold Co. v. Carpenters Dist. Council of Jacksonville and Vicinity*, 417 U.S. 12, 14 (1974) ("We granted certiorari to decide whether the holding of the Florida Supreme Court was consistent with decisions of this Court"); *Wilson v. Schnettler*, 365 U.S. 381, 383 (1961) ("To consider petitioner's claim that the judgment is repugnant to controlling rules and decisions of this Court, we granted certiorari").

I. PUNITIVE DAMAGES WERE UNCONSTITUTIONALLY BASED ON THE OUT-OF-STATE SALES OF AN FDA-APPROVED PRESCRIPTION DRUG

World-wide sales as the sole basis for the amount of the punitive damage award. The punitive award was based on 23 OKLA. STAT. § 9.1(C), which provides that the jury may calculate punitive damages in an amount not exceeding the greatest of (a) $500,000, (b) twice the amount of actual damages awarded, or "the increased financial benefit derived by the defendant as a direct result of the conduct causing the injury to the plaintiff and other persons or entities." R.3823, Tr. 3402. Because the award was more than allowed under the first two options, the only basis for the calculation was the increased financial benefit. The Court of Civil Appeals held that "evidence of the dollar amount of world-wide gross sales of Rezulin – $48 million per month," and "expert testimony" – which in fact is non-existent – "that [Warner-Lambert's] profit margin on Rezulin sales was thirty percent," provided "evidentiary support for the award of punitive damages." App. 17. This was the only "evidentiary support" that the court identified for the award, and the only basis on which to calculate punitive damages that plaintiff's counsel argued to the jury in summation during the punitive damages phase of the trial. Specifically, plaintiff's counsel asserted that Warner-Lambert's profit on Rezulin during the 1997-99 period was "$600 million," and that the profit "over the five weeks that Michael Wakefield took the drug is $21 million." R.3823, Tr. 3410.

In addition to telling the jury to calculate the amount of punitive damages solely from world-wide sales, plaintiff's counsel argued that punitive damages should be

awarded because Warner-Lambert "brought this drug to market" – again referring to the fact that it sold the product nationally. *Id.* at 3403, 3405, 3407. This followed other argument and evidence regarding Warner-Lambert's out-of-state conduct, including allegations about a small percentage of adverse liver events among the nearly two million Rezulin patients nationwide. *See, e.g.*, R.3789, Tr. 917; R.3821, Tr. 3288; R.3823, Tr. 3405-06.

BMW's and State Farm's limitation to in-state transactions. In *BMW*, 517 U.S. at 574, this Court ruled, in the context of a lawsuit involving a nationally distributed product, that under the U.S. Constitution "the scope of the interest in punishment and deterrence that [a state] court may appropriately consider is properly limited" to the interests of that State's citizens, "rather than those of the entire Nation." Before the case reached this Court, the Alabama Supreme Court "found that the jury improperly computed the amount of punitive damages by multiplying Dr. Gore's compensatory damages by the number of similar sales in other jurisdictions," and accordingly ordered a remittitur. *Id.* at 567. There was no evidence that the defendant's out-of-state conduct was unlawful, as in this case where the nationwide sale of Rezulin was authorized by FDA. This Court concluded that the "Alabama Supreme Court, therefore, properly eschewed reliance on BMW's out of state conduct . . . and based its remitted award solely on conduct that occurred within Alabama." *Id.* at 573. That is precisely what the Oklahoma appellate courts refused to do here.

Moreover, in *BMW* the Court found that the Alabama Supreme Court had not gone far enough. Thus, a State may not "punish [a defendant] for conduct that was lawful where it occurred and that had no impact on [that State]

or its residents. Nor may [a State] impose sanctions on [a defendant] in order to deter conduct that is lawful in other jurisdictions." *Id.* Thereafter, in *State Farm* the Court made it clear that punitive damages may not be imposed to punish out-of-state conduct *regardless* whether that conduct would be considered lawful or unlawful where it occurred:

> "A State cannot punish a defendant for conduct that may have been lawful where it occurred. . . . *Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction.* . . . [E]ach State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction."

538 U.S. at 421-22 (emphasis added). *Accord, Continental Trend Resources, Inc. v. OXY USA Inc.*, 101 F.3d 634, 637 (10th Cir. 1996) ("[A]ny penalty must be supported by Oklahoma's 'interest in protecting its own consumers and its own economy.' . . . [W]e read the opinion [in *BMW*] to prohibit reliance upon inhibiting unlawful conduct in other states"). Thus, only the State where the conduct occurred can determine if it was lawful there. And taking the Court's reasoning one step further, only the FDA, and not a jury or court in a single case in Oklahoma, can determine if a prescription drug can lawfully be sold throughout the nation.

Unconstitutionality of the Oklahoma punitive damages statute as applied. The punitive damage instructions were based on 23 OKLA. STAT. § 9.1(C), which authorized punitive damages based on the "increased financial benefit" to the defendant occurring "as a direct result of the conduct

that caused injury to the plaintiff and other persons and entities." On its face, the statute fails to provide juries and courts with standards sufficient to constrain them from making awards calculated on the basis of out-of-state transactions. Thus, the statute fails to limit the "other persons and entities" who may have been caused injury to people in Oklahoma. Moreover, the Oklahoma courts construed the statute to authorize punitive damages based on conduct that did ***not*** cause injury, *i.e.*, the sale of Rezulin to millions of patients who were treated effectively, without injury. If the size of the product line is all that matters, then there are no effective limits on punitive damages in any case involving a nationally marketed, standard product. The statute as interpreted and applied here thus squarely conflicts with *BMW* and *State Farm*, which preclude a punitive damage award based on the general sale of the drug throughout the world.

The erroneous jury instructions. In *State Farm*, 538 U.S. at 422, the Court, citing *BMW*, directed that: "A jury must be instructed . . . that it may not use evidence of out-of-state conduct to punish a defendant for action that was lawful in the jurisdiction where it occurred." Defendants requested instructions, based on *BMW*, that the jury "may not punish defendant for any adverse impact its conduct may have had on anyone other than Mr. Wakefield and the plaintiff," or "for any impact its conduct may have had on individuals in other states." R.3230-31, Nos. 40-41. The trial court denied both instructions. R.3823, Tr. 3393-94. As this Court pointed out in *State Farm*, 538 U.S. at 418: "Vague instructions, or those that merely inform the jury to avoid 'passion or prejudice,' do little to aid the decisionmaker in its task of assigning appropriate weight to evidence that is relevant and evidence that is tangential or

only inflammatory." Here, the trial court's cursory punitive damage charge did not contain even such vague admonitions, let alone the explicit instruction regarding out-of-state conduct required by *BMW*. R.3823, Tr. 3401-02. *Accord, White v. Ford Motor Co.*, 312 F.3d 998, 1020 (9th Cir. 2002) (reversing punitive damage judgment in product liability case; trial court's "refusal to limit the jury to consideration of Nevada's interests, combined with the plaintiffs' lawyers exhortations to let the decision resonate 'across the country,'" resulted in "'a due process violation of the most basic sort' when [the jury] arrived at its punitive damages award").

The perfunctory appellate decision. As this Court stated in *State Farm*, 538 U.S. at 418: "Exacting appellate review ensures that an award of punitive damages is based upon an 'application of law, rather than a decision-maker's caprice.'" (Quoting *BMW*, 517 U.S. at 587.) Here, in response to defendants' argument based on *BMW* and *State Farm*, the Oklahoma Court of Civil Appeals merely stated, without explanation, that "[t]he punitive damages award in this case neither reflects a grossly excessive award, nor attempts to sanction Manufacturing Defendants for conduct legal in other states." App. 18. But because the only measure of punitive damages was *worldwide* Rezulin sales, which the Oklahoma court explicitly recognized earlier in its opinion, defendants plainly were sanctioned for conduct "in other states" and, indeed, other countries. Moreover, under *State Farm*, 538 U.S. at 421, punitive damages may not be awarded to punish out-of-state conduct whether it is lawful or unlawful, so the Oklahoma court mis-stated this Court's test. What is more, the court below did not identify any evidence that these worldwide sales were all "illegal"; there is

no such evidence in the record; and the court could not simply assume that there was anything "illegal" about those sales, particularly where the drug was FDA-approved. *Cf. Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 442 (2001) (in assessing punitive damages, "it would be unrealistic to assume that all of Cooper's sales of the [product] would have been attributable to its misconduct in using a photograph of a modified [product made by Leatherman] in its initial advertising materials").[5]

Absence of any basis for illegality of worldwide sales. Rezulin was sold in the United States pursuant to FDA approval, and also was sold in other countries whose public health agencies approved the drug. The sale of Rezulin was therefore legal. Moreover, worldwide Rezulin sales included sales to the vast majority of patients who benefitted greatly from the drug and had no ill effects. *See, e.g.*, Dr. Hanson's testimony that Rezulin was "an excellent drug," with "really outstanding" effectiveness, which he prescribed for "hundreds of patients" (R.3797, Tr. 1779; R.3798, Tr. 1836); *In re Rezulin Prod. Liab. Lit.*, 210 F.R.D. 61, 66 n.37 (S.D.N.Y. 2002) (even plaintiffs' experts admit that "Rezulin was effective for 95 percent of the patients who ingested it"). Such sales plainly were not "illegal," and cannot be the basis of a punitive damage award.

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[5] If plaintiffs contend, in opposition, that illegality flows from Warner-Lambert's claimed misrepresentations to the FDA in obtaining approval for Rezulin, that argument would be impermissible under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001), which held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law."

The unfairness of calculating punitive damages on the totality of out-of-state sales also is illustrated by the fact that, while there have been some other plaintiffs' verdicts in product liability actions involving Rezulin, a number of juries in other states have returned defense verdicts in such cases.[6] *See BMW*, 517 U.S. at 572 n.17 ("State power may be exercised as much by a jury's application of a state rule of law in a civil lawsuit as by a statute."). There also have been hundreds of cases from around the country dismissed by the federal multi-district Rezulin litigation court (*see, e.g., In re Rezulin Prod. Liab. Litig.*, 2004 WL 1161248 (S.D.N.Y. May 25, 2004)), and more than 20 state court dismissals. Thus, there is no basis to find that Rezulin sales in those states, even sales to the plaintiffs who filed suit in those other states, were "illegal."

Lack of fair notice that worldwide sales can be a basis for punitive damages. In *BMW*, 517 U.S. at 574, this Court explained that due process does not permit out-of-state transactions to be the basis for calculating punitive damages, because: "Elementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice . . . of the severity of the penalty that a State may impose." The *BMW* Court further observed that: "The fact that BMW is a large corporation rather than an impecunious individual does not diminish its entitlement to fair notice of the demands that the several States impose on the conduct of its business. Indeed, its status as

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[6] *Cervantes v. Warner-Lambert Co.*, No. 4122 (Cal. Super. Ct. L.A. Co., May 27, 2004); *Brown v. Warner-Lambert Co.*, No. 348-181927-00 (Dist. Ct. Tarrant Co. Tex. Feb. 18, 2003) (appeal pending); *Shaw v. Warner-Lambert*, No. 209074 (Cir. Ct. Montgomery Co. Md., Feb. 2, 2002); *Mercado v. Warner-Lambert Co.*, No. 2000-42692 (Dist. Ct. Harris Co. Tex. Dec. 17, 2001).

an active participant in the national economy implicates the federal interest in preventing individual States from imposing undue burdens on interstate commerce." *Id.* at 585. Here, particularly in light of *BMW*, these non-resident defendants could not conceivably have predicted that punitive damages would be calculated based on worldwide sales and awarded for a claim on behalf of a single person treated with this FDA-approved drug in Oklahoma, whose FDA-approved warning stated that some patients had experienced serious side effects including liver disease.

The absence of "nexus to specific harm" under State Farm. Nor do world-wide sales have "a nexus to the specific harm suffered by the plaintiff," as required by *State Farm*, 538 U.S. at 422, or an "impact on [that State] or its residents," as required by *BMW*, 517 U.S. at 573. Courts may not award punitive damages "to punish and deter conduct that bore no relation to the [plaintiff's] harm." *State Farm*, 538 U.S. at 422. "Due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis." *Id.* at 423.

The Oklahoma appellate court acknowledged defendants' argument that there is an "insufficient nexus" between the worldwide sales of Rezulin on which the punitive damage award was based and the actual harm to the plaintiff (App. 17), but never responded to it. The court did not identify any nexus between (1) Warner-Lambert's worldwide sales of Rezulin during the time that Mr. Wakefield took the medication and (2) any harm to Mr. Wakefield, and there is no such nexus in the record. In effect, the court below "adjudicate[d] the merits" of "hypothetical claims"

against Warner-Lambert by everyone who purchased and took Rezulin worldwide, including people whose diabetes was controlled by the drug and had no side-effects, and those who filed suit and were found to have no claim. *State Farm*, 538 U.S. at 423. Under this Court's holdings, that is impermissible. Sales of the medication to diabetics who benefitted from it and were not injured – the vast majority of patients who were treated with it – provide no basis for "deterrence" or "retribution," the purpose of punitive damages, and therefore cannot be a basis for a punitive award. *Id.* at 416.

Arbitrariness of the award. In *State Farm*, this Court emphasized that punitive damages may not be awarded arbitrarily. *See, e.g., id.* at 409 ("The Due Process Clause prohibits the imposition of grossly excessive or arbitrary punishments on a tortfeasor"; "punitive damages pose an acute danger of arbitrary deprivation of property"); *id.* at 416-17 (the constitutional concern related to "'arbitrary coercion'"); *id.* at 418 ("'A State can have no legitimate interest in deliberately making the law so arbitrary that citizens will be unable to avoid punishment based solely upon bias or whim'"); *id.* at 429 (the punitive damage award "was an irrational and arbitrary deprivation of the property of the defendant"). This award is entirely arbitrary and illogical. There is simply no relationship between worldwide sales of an FDA-approved prescription drug and an alleged adverse reaction to that drug by a particular person. Nor is there any relationship between the time period for such sales referenced by plaintiff's counsel during her summation – the five weeks during which Mr. Wakefield took Rezulin – and any rational basis for a punitive damage award. By the same reasoning, if the worldwide sales of Rezulin during some particular

period were greater, so that even more diabetics would have benefitted from the medication, then the punitive damages would *increase*. This makes no sense, and is unconstitutionally arbitrary.

Denial of Due Process because of a lack of evidence of the amount of "financial benefit" to defendants in Oklahoma, nationwide or internationally, during the five-week period. The record contains evidence only (1) from annual reports, of the worldwide sales of Rezulin in a calendar year, and (2) from a document prepared in advance of any Rezulin sales, that Warner-Lambert intended to "strive" for a 30% profit on Rezulin. R.3806, Tr. 2090. There is nothing in the record to support the Court of Civil Appeals' statement (without citation) that there was "expert testimony" establishing a 30% profit margin on Rezulin (App. 17), and no evidence of the actual profit margin for Rezulin while it was on the market. Thus, the evidence cannot provide a basis for a finding of "financial benefit" from Rezulin sales, whatever the scope of sales considered, and certainly not in relation to a specific five-week period or within Oklahoma. Plaintiff did not even show the amount of Rezulin sales in Oklahoma, during any period. It is a due process violation to enter a judgment against a party when there is no evidence to support the judgment. *See Thompson v. City of Louisville*, 362 U.S. 199, 206 (1960) (and cases cited in n.13 thereof).

Far-reaching health care policy implications of the decision below. Both *BMW* and *State Farm* expressed concern with the implications of excessive or arbitrary punitive damages awards. Here, the potential consequences to both the parties and the public overwhelm those cited in those two cases. The overriding fact is that the FDA approved Rezulin for nationwide sale. A huge

state court punitive damage award regarding an FDA-approved prescription drug, based on worldwide sales, and contrary to this Court's requirements, undermines the FDA's expert, authoritative determination that – balancing the potential for harm to some patients against the benefits to many – the drug should be approved for sale and should remain on the market. *See BMW*, 517 U.S. at 571 (only Congress has authority "to enact such a policy for the entire nation").

As this Court has recognized, punitive damages have a "devastating potential for harm." *State Farm*, 538 U.S. at 417. The potential for punitive damages based on FDA-approved worldwide sales, faced by any pharmaceutical manufacturer whose product, like all prescription drugs, has risks as well as benefits, is daunting. In pharmaceutical product liability cases such as this, the potential devastating harm is that punitive damage awards will chill the incentive for research and development and diminish the availability of vitally needed new medications for life-threatening diseases, such as diabetes, with severe adverse consequences for public health. *See* Note, "A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals," 103 *Harv. L. Rev.* 773, 774-75 (1990) ("[T]he tort system undermines the availability of pharmaceuticals. Even in the absence of liability judgments, the mere fear of astronomical liability may render a drug uninsurable and consequently unmarketable. In the event a beneficial drug does reach the market . . . litigation costs alone may force the manufacturer to withdraw its product" or "have marked effects on pricing and production.").

Because of the potential for juries to undermine governmental regulation through punitive damage awards,

numerous courts have held that governmental approval or compliance with federal regulations precludes punitive damages.[7] Thus, while FDA approval of a prescription drug and its labeling may not insulate the manufacturer from liability in an individual personal injury action, it should at least preclude a finding that, by selling the drug, the manufacturer was engaged in "illegal" conduct or acted with the malice, recklessness, or wanton disregard for public safety required for punitive damages.

In the circumstances of this case, and many other prescription drug personal injury actions, allowing punitive damages to be calculated from nationwide sales, including sales to those for whom the drug was effective and caused no ill effects, would allow one jury in one case to undermine the regulatory determination made by the FDA, after examining the scientific debate, that the benefits of a drug outweigh the risks. That is the same

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[7] This was a ground for denial of punitive damages argued to the trial court (R.3829, at 14-16) and incorporated into defendants' appellate brief at 29. *See, e.g., Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1059 (11th Cir. 1994), *cert. denied*, 513 U.S. 1111 (1995) (compliance with federal vehicle safety standards precludes a finding of "wantonness"); *Ralph Nader Conn. Citizen Action Group v. Allegheny Airlines, Inc.*, 626 F.2d 1031, 1035 (D.C. Cir. 1980) ("An airline may not be condemned as a wanton wrongdoer for conforming to the standards set and the practices approved by the agency charged with the duty of regulating it"); *Harrison v. Indiana Auto. Shredders Co.*, 528 F.2d 1107, 1124-26 (7th Cir. 1975) (punitive damages reversed where defendant had zoning authority and a permit, and acted on expert advice); *In re Miamisburg Train Derailment Lit.*, 725 N.E.2d 738, 752 (Ohio Ct. App. 1999) (compliance with federal regulation "overwhelm[s] any suggestion that appellees acted with conscious disregard for safety"; affirming summary judgment); *Chrysler Corp. v. Wolmer*, 499 So. 2d 823, 826 (Fla. 1986) (compliance with federal standard for fuel system integrity negates conclusion that defendant acted with "a wanton disregard for life equivalent to manslaughter").

reasoning that has led courts to hold that punitive damages are inappropriate where experts in the scientific community disagree on scientific conclusions, which is clear from the record in this case.[8] Physicians at FDA approval hearings supported the use of Rezulin, and all of the physicians involved in this case who had prescribed Rezulin testified that in their experience the drug was safe and effective – as Mr. Wakefield's own endocrinologist put it, Rezulin was "excellent" and "really outstanding." R.3797, Tr. 1779, R.3798, Tr. 1836. Conversely, plaintiff's sole causation expert, Dr. Julie, admitted that his theory that Rezulin causes hemolytic anemia "has not been tested or confirmed." R.3795, Tr. 1651. Theories that had not been tested or published in 2002 cannot possibly be a predicate for punitive damages based on what Warner-Lambert knew or should have known in 1999.

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[8] This point also was argued to the trial court (R.3829, at 12-14) and incorporated into defendants' appellate brief at 29. *See, e.g., Satcher v. Honda Motor Co.*, 52 F.3d 1311, 1313, 1317 (5th Cir. 1995), *cert. denied*, 516 U.S. 1045 (1996) (punitive damage award vacated because, *inter alia*, "there is a genuine dispute in the scientific community as to whether [motorcycle] leg guards do more harm than good"); *AMPAT/Midwest, Inc. v. Illinois Tool Works Inc.*, 896 F.2d 1035, 1044 (7th Cir. 1990) (affirming order setting aside punitive damages, despite "highly irresponsible behavior" by defendant, given the "disagreement between [experts] over the gravity of the defects" in screws, and about causation); *Berroyer v. Hertz*, 672 F.2d 334, 342 (3d Cir. 1982) ("difference of medical opinion" among experts provided "insufficient support" for punitive damages); *ACandS, Inc. v. Asner*, 686 A.2d 250, 265 (Md. 1996) (reversible error to submit punitive damages to jury where evidence showed "differences of opinion in the state of the art at the time" regarding product risks); *Loitz v. Remington Arms Co.*, 563 N.E.2d 397, 407 (Ill. 1990) (legal standard of " 'flagrant indifference' to public safety" was not satisfied where "expert witnesses disagreed on the safety and suitability of the material" used in shotgun barrels).

In sum, the punitive damage award was impermissibly calculated on the basis of out-of-state conduct – Warner-Lambert's worldwide sales of Rezulin – in conflict with this Court's decisions. In *State Farm*, 538 U.S. at 418, the Court stated that: "Our concerns are heightened when the decisionmaker is presented . . . with evidence that has little bearing as to the amount of punitive damages that should be awarded." In this case, the ***only*** evidence that plaintiff's counsel told the jury it should consider on the amount of punitive damages had ***no*** constitutionally permissible bearing on that determination.

II. THE PUNITIVE DAMAGE AWARD IS UNCONSTITUTIONALLY EXCESSIVE

The amount of the $10 million punitive damage award (nearly seven-fold the compensatory award) conflicts with the teachings of *State Farm*. There, the Supreme Court reiterated that "an award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety," and stated that where (as here) "compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee." *State Farm*, 538 U.S. at 425.

That is exactly the case here. Even assuming *arguendo* that there were some valid basis for punitive damages in the record, there is no basis to exceed the limits on the amount that the Court identified in *State Farm*. As discussed above, this case involves the administration of a widely successful, FDA-approved, lawfully sold prescription drug to a single patient. The risks and benefits of Rezulin are, at the very least, a matter of

legitimate scientific disagreement. Indeed, there was no disagreement on that issue among Mr. Wakefield's own treating physicians, each of whom maintained that it was safe and effective, and none of whom identified it as the cause of Mr. Wakefield's death. As in *State Farm*, 538 U.S. at 427, because there is no evidence "demonstrating harm to the people of [Oklahoma] (other than those directly involved in this case), [this] indicates that the adverse effect on the State's general population was in fact minor."

Under these circumstances, the amount of the award is vastly out of proportion to constitutional requirements and constitutes inappropriate state regulation of an FDA-approved prescription drug on a national basis, further implicating concerns about chilling the incentive for development of pioneering new prescription drugs. *See BMW*, 517 U.S. at 585 (no State "may use the punitive damages deterrent as a means of imposing its regulatory policies on the entire Nation"). The petition should therefore be granted for this reason, as well.

CONCLUSION

The Court should grant the petition for certiorari, summarily reverse, or remand for consideration in light of the requirements of *State Farm* and *BMW*.

Respectfully submitted,

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IN THE COURT OF CIVIL APPEALS
STATE OF OKLAHOMA
DIVISION IV

MARY ROSE WAKEFIELD, individually, and as Personal Representative, Trustee, and Executor of the Estate of Michael Holmes Wakefield, Plaintiff/Appellee, vs. WARNER-LAMBERT COMPANY; PARKE-DAVIS DIVISION OF WARNER-LAMBERT COMPANY, and PFIZER, INC., Defendants/Appellants, and SIMON LEVIT, M.D., and his professional corporation, professional association, unincorporated association, or other business entity, Defendants.	Case No. 99,086 Not For Official Publication (Filed Jul. 20, 2004)

APPEAL FROM THE DISTRICT COURT OF
TULSA COUNTY, OKLAHOMA

HONORABLE SHARRON BUBENIK, TRIAL JUDGE

AFFIRMED

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OPINION BY RONALD J. STUBBLEFIELD, JUDGE:

This is an appeal by defendant drug manufacturers from judgment on jury verdict in a wrongful death product liability action. Based on our review of the record on appeal and applicable law, we affirm.

FACTS AND PROCEDURAL HISTORY

In early 1999, forty-one year old Michael Holmes Wakefield, a sufferer of adult-onset (Type II) diabetes, began taking the prescription drug Rezulin (troglitazone), prescribed by his physician, Dr. Simon Levit, for treatment of the disease. He took the drug for approximately one month and then on March 8, 1999, he presented at the hospital emergency room with symptoms of nausea, vomiting, diarrhea and jaundice. He was admitted to the hospital. Initial tests indicated liver failure, and within the next week Wakefield's (hereafter referred to as Decedent) condition catastrophically deteriorated, and he died on March 15, 1999.

In October 2000, this cause of action was filed by Decedent's wife, Mary Rose Wakefield, acting in various

capacities, and his mother, Mary Louise Wakefield.[1] Plaintiff sued Dr. Levit, claiming he was negligent, and also sued the entities that we shall refer to as the Manufacturing Defendants – Warner-Lambert Company and its Parke-Davis Division (hereafter referred to as WLC), and also Pfizer, Inc., based on the allegation that it was the successor-in-interest of WLC. The claims against the Manufacturing Defendants were that they knew of the highly toxic nature of Rezulin, *had actually downplayed and understated the dangers of the drug in order to obtain approval of the drug by the regulatory Food and Drug Administration (FDA),* and failed to adequately warn physicians and the public of the very high risk of liver damage from use of the drug.

The pretrial litigation was intensive and the case finally went to trial against the Manufacturing Defendants[2] in March 2002. After a three and one-half week trial, with innumerable witnesses and thousands of pages of exhibits, the jury returned two verdicts against the Manufacturing Defendants awarding compensatory damages of $1,550,000 and punitive damages of $10,000,000. The Manufacturing Defendants appeal.

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[1] Defendants filed a motion to dismiss the wrongful death claim of Decedent's mother, Mary Louise Wakefield. However, the disposition of that motion is not apparent from review of the record. In any event, the case proceeded to trial with only the wife, Mary Rose Wakefield, as plaintiff. Thus, hereafter, discussion shall refer only to the singular term "Plaintiff."

[2] The trial was directed solely to liability of the Manufacturing Defendants, and not Dr. Levit. The appealed judgment is solely against "Warner-Lambert, Company, now Pfizer, Inc.," and Dr. Levit is not a party to this appeal.

DISCUSSION OF ISSUES[3]

I. Jury Instruction Issues

The first contention of error is that the Trial Court erred in refusing to give two instructions proffered by Manufacturing Defendants – a condition-versus-cause instruction and a "comment k" instruction regarding unavoidably unsafe products. In reviewing jury instructions on appeal, this Court must consider the instructions as a whole. *Dutsch v. Sea Ray Boats, Inc.,* 1992 OK 155, ¶ 7, 845 P.2d 187, 189. The instructions need not be ideal but must reflect Oklahoma law regarding the subject at issue. *Id.* The salient test for error in instructions is whether the jurors were probably misled regarding the legal standards they should apply to the evidence. *King v. Neal,* 2001 OK CIV APP 11, ¶ 11, 19 P.3d 899, 902. "Before the court will reverse a judgment based on the verdict of a jury because of the giving or refusal to give instructions, it must clearly appear that the instructions given or refused have caused a miscarriage of justice." *Larkins-Warr Trust v. Watchorn Petroleum Co.,* 1946 OK 84, ¶ 0, 174 P.2d 589 (syllabus 2).

A. Condition Versus Cause

The condition-versus-cause argument is based on the defense by Manufacturing Defendants that the actual cause of death of Decedent was not injury from Rezulin but injury resulting from administration of another drug

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[3] Manufacturing Defendants raised fifty propositions of error in their petition in error, but we address only those issues briefed and deem the remaining issues waived. *Hadnot v. Shaw,* 1992 OK 21, ¶ 7, 826 P.2d 978, 981.

to Decedent prior to his death, Rocephin. The instruction offered by Defendants states:

> There is a difference between a direct cause and a condition. If the defendant's act or omission merely creats [*sic*] a condition by which the injury was made possible, and a subsequent independent act caused the injury, the existence of that condition is not the direct cause of the injury. If you find that Rezulin created a condition, but that Rocephin was the direct cause of Mr. Wakefield's death, then you must return a verdict in favor of the Defendants.

Manufacturing Defendants cite *Thur v. Dunkley,* 1970 OK 157, 474 P.2d 403, as authority for this instruction. However, that was a case of clear *intervening* negligence, where a driver had stopped to fix a flat tire, two other cars stopped behind him, and a fourth vehicle then collided with the rear car propelling it into the other stopped automobile. The Oklahoma Supreme Court concluded it was the negligence of the fourth driver that caused the accident, and not the act of the first driver in stopping to fix his tire. The Court spoke of a "series of unfortunate events . . . caused by the intervening negligence" of another party. *Id.* at ¶ 22, 474 P.2d at 406.

In this instance there was no allegation or evidence of true intervening negligence. Plaintiff claimed that Rezulin caused severe damage to Decedent's liver, which led to his death. Manufacturing Defendants claimed that Decedent suffered another medical condition after his hospitalization which caused his death, hemolysis (also called hemolytic anemia), which is defined as the destruction of red blood cells that leads to the release of hemoglobin from within the red blood cells into the blood plasma. *Webster's*

New World Medical Dictionary (2d ed. 2003). However, the testimony of Plaintiff's expert witness, Dr. Neil Julie, was to the effect that a healthy liver would have been able to process and eliminate the excess hemoglobin, but that Decedent's Rezulin-damaged liver could not, leading to his death.

We view this dispute as simply an evidentiary dispute over proximate causation, and not a condition-versus-cause dispute. It was presented to the jury in that posture from the first words of opening statements to the conclusion of the exhaustive trial. However, even if we viewed the administration of Rocephin as a possible intervening cause, we conclude that Manufacturing Defendants' proposed instruction was an incorrect statement of law. As this Court stated in *Conatzer v. American Mercury Insurance Co.*, 2000 OK CIV APP 141, ¶ 20, 15 P.3d 1252, 1257, "not every intervening cause insulates the original negligent actor from liability. . . . When a cause combines with another act or omission to produce an injury or several causes operate to bring about the same result, each negligent actor may be liable for the harm that evolves." Instructions 9 and 10 given by the Trial Court correctly advised the jury regarding intervening causes and, therefore, we conclude that the jury was properly instructed in regard to causation issues. Accordingly, we find that the Trial Court did not err in refusing to give Manufacturing Defendants' proposed condition-versus-cause instruction.

B. The "Comment k" Instruction

Defendants also claim reversible error in the Trial Court's refusal to give an instruction based on Restatement

(Second) of Torts § 402 A, cmt. k (1965). Comment k reads as follows:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable

> product, attended with a known but apparently reasonable risk.

The Oklahoma Supreme Court has acknowledged the possible applicability of a comment k instruction. *Tansy v. Dacomed Corp.,* 1994 OK 146, 890 P.2d 881. However, the Court specifically stated:

> Comment k serves as an affirmative defense when the product is incapable of being made safe under present technology, but the social need for the product warrants its production. . . . There must be at the time of manufacture and distribution "no feasible alternative design which on balance accomplished the subject product's purpose with a lesser risk.". . . .
>
> The defense is available only when the product is properly manufactured and contains adequate warnings. . . . The comment k defense does not apply when the product is defective due to faulty manufacturing or inadequate warnings. . . .

Id. at ¶¶ 13-14, 890 P.2d at 885-86 (citations and footnotes omitted).

In *Hill v. Searle Laboratories,* 884 F.2d 1064 (8th Cir. 1989), a case cited in *Tansy,* the federal court stated:

> The drafters of comment k did not intend to grant all manufacturers of prescription drugs a blanket exception to strict liability. Such an exception was proposed at the American Law Institute meeting where section 402 A and comment k were adopted, but this proposal was defeated. . . . The language of comment k suggests that only exceptional products, albeit such exceptional products are more likely to be found in the field

> of prescription drug products, should be excluded from the strict liability provisions. But more importantly, the example given – the vaccine for the Pasteur treatment of rabies – suggests that only special products, those with exceptional social need, fall within the gamut of comment k.

Id. at 1069 (citation omitted).

Thus, to warrant a comment k instruction, Manufacturing Defendants had the burden of coming forward with evidence establishing that Rezulin was a drug for which there was an exceptional social need, and that it was incapable of being made safe under present technology. In addition, they had the burden of controverting the prima facie case Plaintiff made that the product was defective due to inadequate warnings.[4] We conclude they did neither.

The refusal of the comment k instruction was not an issue the Trial Court took lightly. The Trial Court's comments reflect a studied view of applicable law in regard to application to the facts of this case. When the request for a comment k instruction was made, the Trial Court stated:

> THE COURT: Okay. And, in fact, the Court did tell you last night that I would probably give it but I wanted to go home and, in a quiet closet, read some of the law. And I do think it was a close call, however based upon the comments made in *Hill v. Searle Laboratories,* I came to the conclusion that since it said that this particular Comment k should only apply upon a showing of exceptional social need and the committee had

[4] Discussed, hereafter, in some detail.

> considered applying this rule to all drugs and it was defeated. And even more important that the example they gave was the vaccine for Pasteur treatment of rabies. . . . [T]he federal court says that the suggested special products, those with exceptional social need, fall within the gamut of Comment k. . . . [W]e had some testimony about [Rezulin's] importance to a certain group of diabetics, I don't think it met that level.

From our review of the voluminous record, we simply do not find it clearly appears that the comment k instruction should have been given. There was testimony of doctors that the drug Rezulin worked well for some patients but Manufacturing Defendants' evidence neither addressed the issue of overall product necessity, nor controverted the substantial showing by Plaintiff that Manufacturing Defendants did not reveal substantial damning evidence they had about the drug.

Adequacy of the warnings given by Manufacturing Defendants was the critical issue in this case. Plaintiff presented the expert testimony of Dr. John Gueriguian, a medical doctor, former professor of pharmacology and former FDA medical officer. Dr. Gueriguian testified that he worked on the approvals of more than 100 drugs, including every diabetic medication on the market in America before 1996, and that he was the FDA medical officer actually assigned to Rezulin. His testimony fairly conclusively demonstrated that Manufacturing Defendants did not give adequate warnings, and even supported a conclusion that they manipulated or hid some facts that

might have prevented FDA approval of the drug.[5] Dr. Gueriguian's testimony was not effectively rebutted.

Because we find Manufacturing Defendants did not conclusively establish that Rezulin was demonstrated to be a drug of "exceptional social need," and did not controvert Plaintiff's proof that adequate warnings regarding the drug were not given, we conclude it was not error for the Trial Court to refuse a comment k instruction.

II. The Challenge to the Testimony of Dr. Julie

Manufacturing Defendants next complain that the Trial Court abrogated its "gatekeeper" duty by allowing the testimony of Plaintiff's expert witness, Dr. Neil Julie. We find this challenge to admission of evidence absolutely without merit.

Defendants made several pretrial challenges to Plaintiff's evidence, including the expected testimony of Dr. Julie. The record reflects that the evidentiary issues were subject to considerable scrutiny and that the Trial Court made specific inquiry regarding the qualifications and methodology of Dr. Julie. Clearly, Dr. Julie was highly qualified, as (1) a board-certified internal medicine physician and gastroenterologist who had dealt with several liver disorders; (2) a physician who diagnosed and treated at least three patients with Rezulin-induced liver damage that was reported in journals; and (3) a consultant and clinical researcher who had tested pharmaceutical drugs for gastrointestinal disorders. We agree with Plaintiff's

[5] Once many of these facts came to light, along with other developing evidence regarding the dangers of Rezulin, the drug was removed from the market.

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statement that the witness, because of his expertise, experience and training, was uniquely qualified to give a causation opinion regarding liver injuries.

As for Dr. Julie's methodology used in making the determination that Rezulin caused Decedent's liver injury, which included (1) review of Decedent's medical history; (2) examination of the timing of the injury; (3) creation of a differential diagnosis; and (4) exclusion of other possible causes of Decedent's injury based on experience and review of medical literature, it would pass muster in any court in this land. His methodology, particularly the scope of his inquiry and information gathering, seems to have been superior to that of other testifying expert witnesses, including the witnesses of Manufacturing Defendants. We find no merit to this contention of error.[6]

III. Evidence of WLC's Guilty Plea

Manufacturing Defendants next claim it was reversible error for the Trial Court to allow evidence, for purposes of impeachment, of a 1995 criminal conviction of WLC for falsifying information to the FDA.[7] Manufacturing Defendants argue that the basis of the conviction is unrelated to the facts of this case, and that evidence of a criminal conviction should have been allowed only if the actual company witnesses involved in this case had also been

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[6] On July 14, 2004, Manufacturing Defendants filed a "Notice of Recently Decided Authority." We remain unconvinced that admission of Dr. Julie's testimony constituted an abuse of the Trial Court's discretion.

[7] We reject Plaintiff's claim that the allegation of error was not preserved. The testimony regarding the criminal conviction is in the record.

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involved in the activities which resulted in the criminal conviction.

Title 12 O.S.2001 § 2609 permits use of evidence of a criminal conviction for purpose of attacking the credibility of a witness. The issue is whether the statute should apply to witnesses who are employees of a corporation that has been convicted of a crime. Manufacturing Defendants argue it should not or, at most, evidence of a criminal conviction should only be allowed if a testifying corporate witness is shown to have been directly involved in the activities that led to the corporation's conviction.[8] We tend to agree with Plaintiff's argument that such a limitation upon the rule would actually provide a legal advantage to a corporation which has considerable control over the representatives it involves in any particular lawsuit.[9]

Under the law, corporations generally are recognized as individuals or natural persons. 18 C.J.S. *Corporations* § 2 (1990). However, because a corporation may only act (and testify) through its employees and agents, a blanket denial of application of section 2609 to corporate employees would result in corporations having a legal advantage not available to natural persons. Thus, we conclude that there should be some applicability of the evidentiary law

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[8] Defendants cite *Walden v. Georgia-Pacific Corp.*, 126 F.3d 506 (3rd Cir. 1997), *cert. denied*, 523 U.S. 1074, 118 S. Ct. 1516 (1998), as directly on point. However, the holding of that case generally has not been followed by other courts addressing the issue, and the case did not deal with use of a conviction to impeach specific representations of honesty, trustworthiness, or good character.

[9] A good example of this is WLC's designation in this case of Dr. Daniel Krajewski as its witness about the criminal conviction, although he testified he had no personal knowledge of the facts underlying the conviction.

to corporate representatives. We find that section 2609 should be applicable in the situation where corporate representatives place the company's credibility or reputation for honesty and trustworthiness at issue. Simply put, a criminal conviction of the corporation should be admissible in evidence in regard to credibility of the representatives.

In this instance, the Trial Court instructed the jury that the credibility of witnesses was the only basis for consideration of the evidence of the criminal conviction. We find this was not error.

IV. The Punitive Damages Award

The Manufacturing Defendants next claim the judgment for punitive damages, entered on jury verdict, should be reversed or remitted. They claim the award of ten million dollars is contrary to statutory and constitutional limitations.

The jury was correctly instructed according to the strict terms of 23 O.S. Supp. 2003 § 9.1[10] which, in pertinent part, provides:

> A. In an action for the breach of an obligation not arising from contract, the jury, in addition to actual damages, may, subject to the provisions and limitations in subsections B, C and D of this section, award punitive damages for the sake of example and by way of punishing the defendant based upon the following factors:

[10] The Trial Court instructed according to OUJI-Civil 5.9, which anticipated legislative changes *to the format of* section 9.1 by amendment effective after the date of the trial.

1. The seriousness of the hazard to the public arising from the defendant's misconduct;

2. The profitability of the misconduct to the defendant;

3. The duration of the misconduct and any concealment of it;

4. The degree of the defendant's awareness of the hazard and of its excessiveness;

5. The attitude and conduct of the defendant upon discovery of the misconduct or hazard;

6. In the case of a defendant which is a corporation or other entity, the number and level of employees involved in causing or concealing the misconduct; and

7. The financial condition of the defendant.

B. Category I. Where the jury finds by clear and convincing evidence that:

1. The defendant has been guilty of reckless disregard for the rights of others; or

. . . .

the jury, in a separate proceeding conducted after the jury has made such finding, and awarded actual damages, may award punitive damages in an amount not to exceed the greater of:

a. One Hundred Thousand Dol-

a. One Hundred Thousand Dollars ($100,000.00), or

b. the amount of the actual damages awarded.

. . . .

C. Category II. Where the jury finds by clear and convincing evidence that:

1. The defendant has acted intentionally and with malice towards others; or

. . . .

the jury, in a separate proceeding conducted after the jury has made such finding and awarded actual damages, may award punitive damages in an amount not to exceed the greatest of:

a. Five Hundred Thousand Dollars ($500,000.00),

b. twice the amount of actual damages awarded, or

c. the increased financial benefit derived by the defendant or insurer as a direct result of the conduct causing the injury to the plaintiff and other persons or entities.

Manufacturing Defendants claim the ten million dollar punitive damage award indicates the jury must have used the "increased financial benefit" provision, but that there was no basis in the evidence for such an award. We disagree.

Manufacturing Defendants admit there was evidence

Manufacturing Defendants admit there was evidence of the dollar amount of world-wide gross sales of Rezulin – $48 million per month – but claim this did not give the jury the necessary information to determine "increased financial benefit" because the evidence did not give a basis for determination of actual profit from sales. However, there was expert testimony that WLC's profit margin on Rezulin sales was thirty percent. This testimony, along with that establishing the gross sales of the drug, clearly provided a basis for jury determination of increased financial benefit to Manufacturing Defendants. Thus, we find evidentiary support for the award of punitive damages.

Citing *State Farm Mutual Automobile Insurance Co. v. Campbell,* 538 U.S. 408, 123 S. Ct. 1513 (2003), Manufacturing Defendants claim there is insufficient nexus between the award of punitive damages and the actual harm suffered by plaintiff. They argue that the punitive damages must have been meant to further punish Defendants for the criminal conviction of which the jury was apprised. We reject this contention because the jury was specifically instructed regarding the basis for awarding punitive damages, and, absent specific proof to the contrary, it is presumed that the jury followed its instructions. *Stephens Prod. Co. v. Taylor,* 1997 OK CIV APP 70, ¶ 7, 949 P.2d 301, 302. Here, Manufacturing Defendants' argument is nothing more than conjecture about the basis for the jury's specific punitive damages award. They demonstrate no facts to overcome the presumption the jury followed its instructions and determined punitive damages accordingly.

Manufacturing Defendants also argue that the punitive damages award violates the rule of *BMW of North*

America, Inc. v. Gore, 517 U.S. 559, 116 S. Ct. 1589 (1996). The *Gore* case stands for two principles: (1) states have considerable flexibility in determining the level of punitive damages that they will allow in different classes of cases and in any particular case, and only when the award can fairly be categorized as "grossly excessive," *id.* at 568, 116 S. Ct. at 1595, in relation to these interests, does it enter the zone of arbitrariness that violates the due process clause of the Fourteenth Amendment; and (2) states may not impose economic sanctions on violators of its laws with the intent of changing tort-feasors' lawful conduct in other states. *Id.* at 572, 115 S. Ct. at 1597. Manufacturing Defendants do not specifically elucidate how the result of this case violates either of these principles, and we find it does not. The punitive damages award in this case neither reflects a grossly excessive award, nor attempts to sanction Manufacturing Defendants for conduct legal in other states. We find no merit to this contention of error.

V. Judgment Against Pfizer

Manufacturing Defendants' final argument is that there was no basis for the judgment against Pfizer because it did not develop, manufacture or distribute Rezulin. However, they admit that Pfizer "acquired" WLC in 2000. Under Oklahoma law, surviving corporations are liable for torts of merged corporations. *Investors Preferred Life Ins. Co. v. Abraham,* 375 F.2d 291, 293 (10th Cir. 1967). The demonstrated and/or admitted facts were a sufficient basis to impose liability upon Pfizer under this rule.

CONCLUSION

We find none of the contentions of error of Manufacturing Defendants availing of reversal of the judgment on jury verdict. Accordingly, the judgment must be affirmed.

AFFIRMED.

TAYLOR, P.J., and GOODMAN, J., concur.

July 20, 2004

IN THE SUPREME COURT OF THE STATE OF OKLAHOMA

Monday, November 1, 2004

THE CLERK IS DIRECTED TO ENTER THE FOLLOWING ORDERS OF THE COURT:

99,086 Mary Rose Wakefield, individually, and as Personal Representative, Trustee of the Estate of Michael Holmes Wakefield and Mary Louise Wakefield v. Warner-Lambert Company, et al.
Petition for certiorari is denied.
CONCUR: Watt, C.J., Opala, V.C.J., Lavender, Hargrave, Kauger, Edmondson, Taylor, Colbert, JJ.
NOT PARTICIPATING: Winchester, J.

* * *

UNITED STATES CONSTITUTION, FOURTEENTH AMENDMENT

Section 1. All persons born or naturalized in the United States and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

OKLAHOMA STATUTES, TITLE 23

§ 9.1. Punitive damages awards by jury

A. In an action for the breach of an obligation not arising from contract, the jury, in addition to actual damages, may, subject to the provisions and limitations in subsections B, C and D of this section, award punitive damages for the sake of example and by way of punishing the defendant based upon the following factors:

1. The seriousness of the hazard to the public arising from the defendant's misconduct;

2. The profitability of the misconduct to the defendant;

3. The duration of the misconduct and any concealment of it;

4. The degree of the defendant's awareness of the hazard and of its excessiveness;

5. The attitude and conduct of the defendant upon discovery of the misconduct or hazard;

6. In a case of a defendant which is a corporation or other entity, the number and level of employees involved in causing or concealing the misconduct; and

7. The financial condition of the defendant.

B. Category I. Where the jury finds by clear and convincing evidence that:

1. The defendant has been guilty of reckless disregard for the rights of others; or

2. An insurer has recklessly disregarded its duty to deal fairly and act in good faith with its insured; the jury, in a

separate proceeding conducted after the jury has made such finding and awarded actual damages, may award punitive damages in an amount not to exceed the greater of:

a. One Hundred Thousand Dollars ($100,000.00), or

b. the amount of the actual damages awarded.

Any award of punitive damages under this subsection awarded in any manner other than as required in this subsection shall be void and reversible error.

C. Category II. Where the jury finds by clear and convincing evidence that:

1. The defendant has acted intentionally and with malice towards others; or

2. An insurer has intentionally and with malice breached its duty to deal fairly and act in good faith with its insured;

the jury, in a separate proceeding conducted after the jury has made such finding and awarded actual damages, may award punitive damages in an amount not to exceed the greatest of:

a. Five Hundred Thousand Dollars ($500,000.00),

b. twice the amount of actual damages awarded, or

c. the increased financial benefit derived by the defendant or insurer as a direct result of the conduct causing the injury to the plaintiff and other persons or entities.

The trial court shall reduce any award for punitive damages awarded pursuant to the provisions of subparagraph c of this paragraph by the amount it finds the defendant or

insurer has previously paid as a result of all punitive damage verdicts entered in any court of this state for the same conduct by the defendant or insurer. Any award of punitive damages under this subsection awarded in any manner other than as required in this subsection shall be void and reversible error.

D. Category III. Where the jury finds by clear and convincing evidence that:

1. The defendant has acted intentionally and with malice towards others; or

2. An insurer has intentionally and with malice breached its duty to deal fairly and act in good faith with its insured; and the court finds, on the record and out of the presence of the jury, that there is evidence beyond a reasonable doubt that the defendant or insurer acted intentionally and with malice and engaged in conduct life-threatening to humans,

the jury, in a separate proceeding conducted after the jury has made such finding and awarded actual damages, may award punitive damages in any amount the jury deems appropriate, without regard to the limitations set forth in subsections B and C of this section. Any award of punitive damages under this subsection awarded in any manner other than as required in this subsection shall be void and reversible error.

E. In determining the amount, if any, of punitive damages to be awarded under either subsection B, C or D of this section, the jury shall make the award based upon the factors set forth in subsection A of this section.

F. The provisions of this section are severable, and if any part or provision thereof shall be held void, the decision of

the court shall not affect or impair any of the remaining parts or provisions thereof.

G. This section shall apply to all civil actions filed after the effective date of this act.

(5)

Supreme Court, U.S.
FILED
APR 4 - 2005
OFFICE OF THE CLERK

No. 04-1047

IN THE

Supreme Court of the United States

WARNER-LAMBERT CO., *et al.*,

Petitioners,

v.

MARY ROSE WAKEFIELD,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE OKLAHOMA COURT OF CIVIL APPEALS

BRIEF IN OPPOSITION

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INTRODUCTION

This is a state court, state law product liability case involving a tragic death caused by Rezulin®. Rezulin was a prescription drug the United States Food and Drug Administration ("FDA") requested be withdrawn from the market after just three years of sales. Michael Wakefield died from Rezulin-induced liver failure, precisely the condition prompting the withdrawal. Michael's widow, Mary Louise Wakefield ("Wakefield"), brought suit against Warner-Lambert Company, its Parke-Davis Division and Pfizer Inc., its successor in interest ("WLC"), the manufacturer of Rezulin. After a three-and-a-half week bifurcated trial, an Oklahoma jury awarded compensatory damages of $1.55 million and punitive damages of $10 million. In unanimously affirming the verdict, the Oklahoma Court of Civil Appeals rejected the plethora of issues WLC raised on appeal. This opinion is unpublished and has no precedential importance. The Oklahoma Supreme Court, likewise acting unanimously, denied WLC's petition for certiorari.

WLC raises only two alleged errors here. First, WLC contends the punitive damage award is excessive and unconstitutional "because it was calculated from world-wide gross sales" in supposed conflict with *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003) and *BMW of North America v. Gore*, 517 U.S. 559 (1996). Petition for Writ of Certiorari ("Pet.") at (i). Second, WLC asserts that the punitive damage award is excessive when compared to the compensatory damage award. *Id.*

WLC's first contention is without merit for the following reasons:

(a) WLC failed to adequately preserve its points of error. WLC's question essentially asks this Court to find one of the following arguments to be correct, yet WLC failed to properly present any of these issues to the Oklahoma Supreme Court in its state Petition for Certiorari (*See Appendix*):

(i) Whether it was unconstitutional or inappropriate for the jury to have considered financial evidence of WLC's Rezulin sales when deciding the appropriate punishment for WLC's intentional and malicious conduct because some of that profit was derived from sales outside of Oklahoma. WLC introduced the very evidence of its worldwide sales of which it now complains. WLC asserts in its Petition to this Court that WLC's financial benefit from Rezulin or "annual gross sales were taken from Warner-Lambert's annual reports" but fails to mention that such annual reports were admitted by WLC itself. Pet. at 7. WLC never redacted any figures on those documents and failed to ask that the documents be admitted for a limited purpose. WLC now argues that the jury should have considered only Oklahoma sales in assessing the appropriate amount of punitive damages to award but WLC never sought to limit its admitted evidence to only Oklahoma sales. WLC should not now be permitted to complain of its own mistakes.

(ii) Whether the jury should have received different jury instructions as to the definitions of certain words contained in the Oklahoma's punitive damage statute or how to properly consider the evidence admitted by WLC regarding its world-wide sales. Before the Oklahoma appellate courts, WLC failed to challenge the jury instructions on punitive damages. Instead, WLC now asks this Court to be the first appellate court to review this issue.

(iii) Whether there was sufficient evidence of WLC's increased financial benefit to justify the punitive damage award. WLC did not raise any issues concerning the sufficiency of the evidence to support the punitive award in its Petition for Certiorari to the Oklahoma Supreme Court and objected to none of the evidence or testimony on this issue. WLC's belated complaints to this Court should fall on deaf ears.

(iv) Whether the Oklahoma punitive damages statute is unconstitutional as it fails to provide adequate definitions for some of the statutory language. WLC never challenged the constitutionality of the statute in its state court Petition for Certiorari on any grounds.

(v) Whether there was sufficient evidence that WLC's worldwide Rezulin sales were gained through illegal conduct. WLC did not preserve this objection (or any of the ramifications of that argument now articulated) in the appellate process.

(vi) Whether WLC had fair notice that worldwide sales could be a basis for a punitive damages award in Oklahoma. WLC never articulated this argument before.

(b) No evidence of unrelated or irrelevant "out-of-state conduct" was introduced, let alone argued, as the basis for a punitive damages award. In the *State Farm* and *BMW* cases, the plaintiffs introduced evidence of misdeeds that occurred outside the plaintiff's home states and affected residents of states outside the plaintiff's home state to prove an alleged pattern of reprehensible conduct. By contrast, each intentional misdeed proven in this case affected Oklahoma residents including Mr. Wakefield (notwithstanding that it affected residents of other states as well). The misconduct here is WLC's intentional, malicious and fraudulent concealment of the harms of Rezulin in its labeling, advertising and other marketing. These are misdeeds that cut across state lines and cannot be deemed to have occurred in any one state as opposed to any other. The evidence at trial was that WLC intentionally concealed important information about Rezulin's liver toxicity from prescribing physicians, including Michael Wakefield's doctor. Because of WLC's false representations, Michael Wakefield was prescribed Rezulin that caused his death. All conduct evidence introduced at trial was directly related to and causative of Wakefield's injury. Further, WLC does not cite this Court to a shred of evidence that it is

legal in any other state to intentionally conceal safety information and deliberately misrepresent a drug's risks in order to induce sales.

"Out-of-state sales" are distinct from "out-of-state misconduct." *State Farm* and *BMW* stand for the proposition that a defendant should not be punished for particular acts of misconduct that occurred in other states. WLC asks this Court to confuse sales data or financial information appropriate for determining the appropriate amount for a punitive damage award with judgment by a jury of a company's out-of-state conduct. These are two wholly separate concerns. The act of factoring overall profitability into a punitive damages award simply seeks to make the punishment commensurate with the wrongdoer's wealth. Under WLC's contorted reasoning, if a pharmaceutical company deliberately misrepresented a drug in a nationwide advertising campaign but only sold one pill of that drug in a certain state causing death to the state resident, that state has no power to punish that defendant for its intentional and malicious acts which caused a resident's death beyond the earnings for that one pill. This argument asks the Court to remove a jury's ability to consider net worth or sales data in order to set a punitive award that would be sufficient to deter similar future conduct in that state.

(c) WLC offers no evidence suggesting the evidence of worldwide sales factored into the jury's consideration, let alone that it was likely dispositive to the jury's decision. The jury was clearly permitted under the Oklahoma punitive damages statute to consider WLC's net worth or financial condition when assessing the amount of punitive damages necessary to punish WLC for its intentional and malicious conduct. WLC now asks this Court to speculate that the jury also used this financial information to punish WLC for lawful out-of-state conduct. As the Oklahoma Court of Civil Appeals has already told WLC, its "argument is nothing more than

conjecture about the basis for the jury's specific punitive damages award. The Manufacturing Defendants demonstrate no facts to overcome the presumption the jury followed its instructions and determined punitive damages accordingly." COCA Opinion Pet. App. at 17.

Moreover, WLC's second presented question is not worthy of review because the punitive damage award is not disproportionate to the compensatory damage award. This is especially true since the punitive damage award is for misconduct that caused incapacitating death rather than mere economic damage such as the need for automobile repair.

In light of the significant waiver issues present in this case, it is a uniquely poor candidate for certiorari. WLC disguises what is nothing more than a challenge to the sufficiency of the evidence, the admissibility of its own evidence or the adequacy of the trial court's jury instructions (arguments which were not preserved) into a constitutional argument. WLC does not even claim that there is a division of authority among the lower courts but merely asserts that the punitive damage award is in conflict with this Court's *State Farm* and *BMW* precedent. WLC asks this Court to now expand those holdings to exclude not just punishment by a state for irrelevant and unrelated out-of-state conduct but also to prohibit consideration by a jury of relevant and material financial or net worth evidence (which in this case was introduced by WLC itself).

COUNTER STATEMENT OF THE CASE

The questions raised in WLC's petition for certiorari relate solely to the ***amount*** of the punitive damages awarded. WLC never argues that Wakefield is not entitled to punitive damages and does not contest that WLC's conduct was intentional and malicious. However, WLC includes pages of what is essentially jury argument on factual and evidentiary issues in its Petition to the Court. Wakefield will thus first respond to those assertions

even though most of them have little or no bearing on the two questions presented.

Background – General Liability Evidence. Rezulin was on the market only three short years before WLC agreed to the FDA's request that it be removed because of the drug's excessive liver risks. No other oral diabetic medication on the market causes a similar level, severity or frequency of liver injuries. No other diabetic medication has been removed from the market because of its toxicity.

At trial, the jury heard evidence on more than two dozen examples of WLC's "deliberate false statements, acts of affirmative misconduct and concealment of evidence of improper motive." *BMW*, 517 U.S. at 560. On a number of occasions, WLC specifically misrepresented the liver toxicity of Rezulin, intentionally concealed data from its Rezulin studies and affirmatively misled physicians about the drug's risks. The jury found by clear and convincing evidence that WLC acted "intentionally and with malice towards others." WLC does not challenge the jury's findings on these points.

Lawsuits were filed both while Rezulin was on the market and after its withdrawal. In several trials, juries strongly condemned WLC's conduct concerning Rezulin and found WLC's wrongdoing to be intentional and malicious. Now, however, the litigation is virtually over. WLC has settled the vast majority of the pending Rezulin cases and paid compensation to tens of thousands of injured people. There are no other appeals pending. Only a small fraction of the cases still remain for resolution.

The bulk of the Wakefield's general liability and causation evidence came from Dr. John Gueriguian ("Gueriguian"). Gueriguian, a former FDA medical officer, had worked on the approvals of more than one hundred drugs including every

diabetic medication on the market in America before 1996. R. 3785, Tr. 391-92, 406. From 1989 to 1996, Gueriguian was the actual medical officer assigned to the drug Rezulin and had factual experience working with WLC and this drug. R. 3785, Tr. 392, 444; R. 3827, PX-1259. Gueriguian is a medical doctor and a former professor of pharmacology. He completed a fellowship at Harvard University in endocrinology and has specialized medical training in internal medicine, biochemistry and chemistry. R. 3785, Tr. 296, 395-403. Because of his education, experience and personal involvement with Rezulin he was specifically qualified to offer his opinions. A cursory review of Gueriguian's trial testimony reveals the extent of WLC's deceit and unconscionable conduct in this case.

WLC purposefully concealed the signals of Rezulin's liver toxicity uncovered in the drug development process, marketed Rezulin as a drug with "side effects comparable to placebo" and then consistently assured physicians that Rezulin had an excellent safety profile, presenting little risk to patients. R. 3788, Tr. 765-66. WLC knew that the reality was the exact opposite. Gueriguian painstakingly educated the jury about the steps taken by drug companies to develop a new drug and WLC's decision to conceal the information learned through such testing. R. 3786, Tr. 435-39. At each of these steps (cell testing, animal testing and human studies), Rezulin showed a clear signal of liver and blood toxicity. Instead of acting responsibly and halting development (like two other companies did with similar compounds), WLC forged ahead to rush Rezulin to market in order to capitalize on the "first to market" profits and chose to conceal these results from the prescribing physicians. R. 3789, Tr. 910-16; R. 3787, Tr. 660-61; R. 3786, Tr. 457-59, 462-65; R. 3827, PX-2517, 2613, 3623.

Pre-approval cell testing showed that Rezulin-treated cells died quickly and in an unpredictable manner – a "highly unusual" finding. R. 3786, Tr. 465-69; R. 3827, PX-4058. Further cell

testing confirmed that Rezulin was liver toxic even at low concentrations. R. 3786, Tr. 469, 485-508; R. 3827, PX-1594. Cell testing done before the drug was even approved showed an alarming range and severity of liver toxicity. R. 3812, Tr. 2526-55. WLC deliberately hid these results from the doctors throughout the time that the drug was being sold and published these findings only after removing Rezulin from the market. *Id.*

Animal studies showed that Rezulin was liver toxic in every animal species tested. R. 3786, Tr. 509, 511; R. 3827, PX-429, 439, 441, 917, 2726. These liver effects showed up at concentrations even below anticipated human doses – a finding that was "very unique" and not seen by Gueriguian in his "20 years at the FDA for any other drug." R. 3786, Tr. 521. Both Gueriguian and WLC's own FDA expert, Dr. Garvey, admitted that the animal studies signaled Rezulin's liver injury potential. R. 3787, Tr. 564; R. 3804, Tr 1998. WLC again chose never to warn doctors about these findings and deliberately never conducted human studies to better understand the drug's liver toxicity potential. R. 3787, Tr. 660-61; R. 3827, PX-165; R. 3804, Tr. 2001.

Although the human testing further confirmed Rezulin's liver toxicity, WLC systematically misrepresented this data. For example, when WLC's human studies showed that fifty-six (56) volunteers had suffered liver injury, WLC chose to report that there were only fourteen (14) patients with abnormal liver enzyme ("ALT") levels. R. 3788, Tr. 720; R. 3788, Tr. 726-27; R. 3827, PX-2524. This is a serious violation of a drug company's duty to report its study results accurately. Dr. Garvey, WLC's own FDA expert, testified that for a drug company to make this type of incorrect representations about clinical trial data "would be criminal." R. 3804, Tr. 2001-02.

1. WLC repeatedly altered the results of its human studies and concealed such data from physicians. R. 3786, Tr. 532-33; R. 3827, PX-127, 128, 133, 1281, 3660. One important example involved Dr. Janet McGill ("McGill") and the Rezulin "042" study. McGill was WLC's principal investigator at one of the five sites set up for this human study. She later came forward and reported to the FDA and Congress that WLC had falsified the data from her trial site. R. 3787, Tr. 686-88. WLC's final study report on the 042 trial stated that there were no liver abnormalities seen in the entire study (which included five testing sites). R. 3787, Tr. 678-79; R. 3827, PX-744. In reality, there were four patients with elevated ALT levels at McGill's site alone. R. 3787, Tr. 678-85. McGill further revealed that WLC had coerced her to change how she defined the adverse events she observed as well as her causation assessments regarding the relationship between Rezulin and those events. R. 3788, Tr. 700-01; R. 3787, Tr. 686-88; R. 3827, PX-735.

2. WLC concealed clinical trial deaths. Human study data is awarded great importance because the patient volunteers are more carefully monitored and evaluated than the general population to protect them from injury. Despite these precautions, three volunteers in the Rezulin human studies died from liver injuries. R. 3788, Tr. 840-70. The first of these deaths occurred in May 1998 in a study conducted by the National Institute of Health ("NIH"). R. 3788, Tr. 831-33. Both WLC's liver expert and the NIH's panel of three esteemed liver specialists concluded that Rezulin caused the patient's liver injury. R. 3788, Tr. 835-40. This was an important finding because this volunteer had two separate medical problems occurring simultaneously (like Wakefield) and it was the patient's liver dysfunction that limited her ability to combat the other issue, ultimately leading to her death (again, like Wakefield). R. 3814, Tr. 2826-28; R. 3827, PX 671. Instead of revealing these findings, WLC issued a statement to the public and prescribing physicians contradicting the experts' opinions and expressly stating that the patient died

"due to complications unrelated to the study or the medication." R. 3789, Tr. 842; R. 3827, PX 2049. Further, WLC never included information or warnings about any of these clinical trial deaths in the Rezulin label. R. 3789, Tr. 915.

3. WLC consistently misrepresented and understated Rezulin's risk statistics. While WLC's own statistics (based upon the clinical trial deaths alone) showed that Rezulin's risk of a fatal liver event was 1 in 5,800, WLC never warned doctors about this risk level. R. 3789, Tr. 875; R. 3827, PX-3196. Instead, the company reassured doctors by misrepresenting that the risk of liver transplantation or death from Rezulin was rare and in the order of 1 in 60,000. R. 3789, Tr. 894; R. 3827, PX 227.

4. Rezulin warnings were deliberately inaccurate. For example, the label reassured doctors that there were only forty-eight (48) patients with elevated ALTs in the human studies. R. 3827, PX-165. WLC knew that there were actually eighty-eight (88) such patients but chose to hide that data. R. 3788, Tr. 730-32; R. 3827, PX-3663; R. 3788, Tr. 735-36; R. 3789, Tr. 854; R. 3793, Tr. 1417. Second, the label represented that there were only two cases of jaundice seen in the clinical trials, but WLC's corporate representative, Dr. Robert Zerbe, admitted this representation was "wrong" and not a "correct statement." R. 3814, Tr. 2820-23. Third, WLC represented that Rezulin liver injuries were "rare" even though trial evidence confirmed that this description was "highly inappropriate" since the accurate statistics were as high as one serious liver injury in every three hundred (300) people. R. 3789, Tr. 908-11.

5. Financial motive. The jury also heard evidence about WLC's financial motive. In 1996, WLC was in deep financial trouble: its stock price was low, sales were flat, the company had poor profitability, an important patent had expired (exposing WLC to generic competition), and WLC had experienced

research and development failures. Manufacturing problems led to a consent decree that cost WLC a $1 billion loss in sales. R. 3806, Tr. 2183-89; R. 3814, Tr. 2760-61; R. 3827, PX-1401. WLC's hope for financial rescue was Rezulin: a "project born of necessity, a sense of urgency created by the need for sheer survival." R. 3827, PX-1415. WLC was under grave financial pressure to bring Rezulin to market with as few warnings as possible in order to maximize its sales potential. WLC intentionally concealed the drug's liver toxicity from physicians and patients to induce tremendous sales. WLC's stock soared and the drug earned more than $2 billion. R. 3806, Tr. 2156-59, 2100-01.

6. Efficacy. WLC knew that Rezulin had lower efficacy and higher risks in relation to the other oral diabetic drugs available at the same time. R. 3788, Tr. 738-41; R. 3789, Tr. 913-14. Yet WLC's Petition cites repeatedly to unsubstantiated anecdotal or observational comments about Rezulin's efficacy while refusing to address the scientific statistical evidence presented at trial that the other two classes of diabetic medications available had significantly greater efficacy. *Id.*

Efficacy as measured by:	***Rezulin***	***Metformin/ Glucophage***	***Sulfonylureas***
Percentage reduction in blood sugar levels (HbA1C)	**1.2 – 1.5%**	**1.8% - 2.2%**	**1.8 – 2.2%**

Background – Michael Wakefield. Wakefield died in the prime of his life, at age 42. He was a high wage earner, making $24,000 a month at the time of this death. R. 3801, Tr. 1937. Expert testimony at trial established that loss of wages alone resulted in his estate suffering economic damages of more than $5 million. R. 3801, Tr. 1952.

Michael Wakefield died in intensive care. As his liver injury escalated, the ammonia levels in his brain built up, causing confusion. Eventually, the doctors were forced to tie him to his hospital bed. R. 3808, Tr. 2249. He turned yellow from jaundice. On the morning of his death, the doctors discussed a liver transplant with his family. However, Wakefield died before that surgery could be performed. R. 3808, Tr. 2252.

Substantial evidence revealed that Rezulin proximately caused Wakefield's death. The Oklahoma Court of Civil Appeals found that Plaintiff's expert, Dr. Neil Julie's ("Julie") expertise, experience and training made him highly qualified to offer causation opinions concerning Rezulin-induced injuries. Julie received his medical degree from Cornell University, earning double board certification in internal medicine and gastroenterology. R. 3794, Tr. 1522. He is experienced in toxic exposure causation assessments. R. 3794, Tr. 1523. In addition to treating patients in his medical practice, Julie is also a consultant, a clinical researcher for pharmaceutical companies, and devotes a substantial part of his practice to the study of liver diseases. R. 3794, Tr. 1526. Julie published the first medical article on Rezulin-induced liver toxicity. Before becoming involved in the Rezulin litigation, Julie diagnosed and treated three patients with Rezulin-induced liver damage. R. 3794, Tr. 1527. Case reports on two of these patients were published in the prestigious medical journals *Annals of Internal Medicine* and *American Journal of Gastroenterology*. R. 3794, Tr. 1527-31; R. 3795, Tr. 1568, 1577.

Both Julie and WLC's expert (Dr. Joel Greenson) agreed that Wakefield's condition involved multiple factors uniquely characteristic of a Rezulin liver injury. R. 3827, PX-2241. Wakefield had ALT levels in his blood that were more than four times normal limits. Not surprisingly, he developed jaundice. R. 3795, Tr. 1601-03. Pathology showed degenerative liver changes, necrosis (liver cell death), active hepatitis (liver

inflammation), a lack of zonal pattern to the necrosis and eosinophils (a finding unique to Rezulin injuries). R. 3795, Tr. 1601-04; R. 3804, Tr. 2049-50; R. 3810, Tr. 2354-59; R. 3827, PX-2241. Wakefield's autopsy showed prominent cholestasis, a condition commonly seen in Rezulin-induced liver injuries. R. 3795, Tr. 1576, 1605.

WLC argues here (as though it is asking this Court to become a second jury) that Wakefield died from hemolytic anemia caused by another drug, Rocephin. However, the medical records showed that the hemolysis blood disorder started *before* Wakefield ever received Rocephin and thus could not have been caused by Rocephin. R. 3795, Tr. 1596-98. While Julie testified during cross-examination that Rezulin can cause hemolytic blood disorders like that suffered by Wakefield, he concluded that issue was irrelevant because Wakefield's liver disorder was caused by Rezulin. R. 3795, Tr. 1610-11. Julie further testified that Wakefield would not have died *but for* his Rezulin-induced liver dysfunction, no matter what the cause of the blood hemolysis. R. 3795, Tr. 1610-11.

Procedural Background. Mary Rose Wakefield filed a wrongful death lawsuit against WLC in October of 2000 asserting claims under theories of product liability, negligence and intentional misrepresentation and fraud. Wakefield originally also sued the decedent's prescribing physician but dismissed him before jury selection. WLC then removed the case to federal court on the first day of trial in an attempt to avoid the long-confirmed trial setting. The federal district court ruled within hours of such removal that there was no fraudulent joinder of the physician or "ploy to defeat diversity" and remanded the case by the end of the day.[1]

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1. In his Order of Remand, Judge Ellison rejected Warner-Lambert's arguments for removal since he was, "not convinced by the facts recited by Defendants that the suit against [defendant] Dr.

(Cont'd)

The jury found in favor of the plaintiff, awarded compensatory damages and further held that WLC had acted intentionally and maliciously. During a separate punitive damages phase, the jury was instructed that it could award punitive damages "for the sake of example and by way of punishing the defendant" based on seven factors.[2] After further deliberation, the jury returned a punitive damages award of ten million dollars ($10,000,000).

WLC filed post-verdict briefing which raised forty-four (44) individual points of error, challenging the admission of evidence, the sufficiency of the evidence to support the jury's verdicts as well as various procedural arguments. R. 3294-3464. The trial court denied WLC's requested post-trial relief. On appeal, WLC abandoned many previously claimed points of error and focused its appeal on the admission of one expert's testimony, two jury instructions, the admission of the corporation's felony conviction and a challenge to the punitive damages award.[3] As for the punitive award, WLC devoted only three-and-a-half pages to five specific challenges.

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Levit was in bad faith, or was intended solely to defeat removal, or even that Plaintiffs never intended to pursue the suit against Dr. Levit to its completion. In this regard, the Court gives great weight to Defendant's admission that they are not arguing that there was no factual basis for the claim against Dr. Levit. With this admission, Defendants effectively concede that Dr. Levit was not fraudulently joined in order to defeat jurisdiction."

2. (1) Seriousness of the hazard to the public arising from the defendant's misconduct; (2) the profitability of the misconduct to the defendant; (3) the duration of the misconduct and any concealment of it; (4) the degree of the defendant's awareness of the hazard and its excessiveness; (5) the attitude and conduct of the defendant upon the discovery of the misconduct or hazard; (6) the number and levels of corporate employees involved in causing or concealing the misconduct; and (7) the financial condition of the defendant. OKLA. STAT. TITLE 23 § 9.1A

3. Under Oklahoma law, all appeals are filed with the Oklahoma Supreme Court which either hears the appeal itself or refers it to the

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As to the punitive damages award, the Oklahoma Court of Civil Appeals found that "the jury was correctly instructed according to the strict terms of 23 O.S. Supp. Paragraph 9.1." Pet. App. 14. Second, the Oklahoma Court of Civil Appeals disagreed with WLC's challenge to the sufficiency of the evidence to support the punitive award. The Oklahoma Court of Civil Appeals actually cited to just a fraction of the financial evidence introduced at trial to demonstrate that "this testimony, along with that establishing the gross sales of the drug, clearly provided a basis for jury determination of increased benefit to Manufacturing Defendants." Pet. App. at 17. In conclusion, the court found adequate "evidentiary support for the award of punitive damages." *Id.*

The court then addressed WLC's arguments under *State Farm* that there was an "insufficient nexus between the punitive damages and the actual harm suffered by plaintiff." Pet. App. at 17. The Oklahoma Court of Civil Appeals again rejected this contention because "the jury was specifically instructed regarding the basis for awarding punitive damages and absent proof to the contrary, it is presumed that the jury followed its instructions." *Id.* The court further found that WLC's argument was "nothing more than conjecture" since WLC "demonstrate no facts to overcome the presumption the jury followed its instructions and determined punitive damages accordingly." *Id.*

Finally, the court addressed WLC's argument that the award violated the guidelines outlined in *BMW*. After setting forth the principles of *BMW*, the court concluded that:

> Manufacturing Defendants do not specifically elucidate how the result of this case violates either of these principles, and we find it does not. The punitive damages award in this case neither reflects a

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Oklahoma Court of Civil Appeals for disposition (as the Oklahoma Supreme Court did here). A petition for writ of certiorari may then be filed with Oklahoma Supreme Court.

> grossly excessive award nor attempts to sanction Manufacturing Defendants for conduct legal in other states. We find no merit to this contention of error.

Pet. App. at 18

In WLC's Petition for Certiorari to the Oklahoma Supreme Court, WLC narrowed its points of error on the punitive damages issue even further. WLC devoted less than two and one-half pages of its Petition to challenges to the punitive damages award and severely restricted its objections. *See Appendix*. WLC failed to preserve many of the issues now raised before this Court.

REASONS FOR DENYING THE PETITION

I. WLC Has Failed To Demonstrate That Its Federal Claims Were Properly Presented To The Oklahoma Courts.

Under "well settled" doctrine animated by federalism concerns, this Court does not review the final judgments of state courts unless "'the record as a whole shows either expressly or by clear implication that the federal claim was adequately presented in the state system.'" *Board of Dir. of Rotary Int'l v. Rotary Club of Duarte*, 481 U.S. 537, 549-50 (1987) (citation omitted). Where a state supreme court's opinion is silent on a federal issue, this Court properly assumes that the issue was not properly presented and will not grant a writ of certiorari unless the petitioner demonstrates that the state court had "'a fair opportunity to address the federal question that is sought to be presented.'" *Adams v. Robertson*, 520 U.S. 83, 86-87 (1997) (per curiam) (citation omitted) (dismissing writ of certiorari as improvidently granted). To confirm that an issue was fairly presented to the state courts, this Court requires the petitioner to establish that the claim was "raised at the time and in the manner required by state law," and that the claim was presented "with fair precision and in due time." *Id.*

WLC has not and cannot show that it raised its claims in the manner required. WLC identified a number of points of error regarding punitive damages in its post-trial briefing but by the time WLC filed its Petition for Certiorari with the Oklahoma Supreme Court, WLC made a tactical decision to significantly narrow its punitive award issues. All points of error not raised in the petition for error are deemed waived under Oklahoma procedural rules. *Peters v. Golden Oil Co.*, 600 P.2d 330 (Okla. 1979) ("Assignments of error which are not argued or supported in brief with citations of authority will be considered and treated as waived by this Court")[4]; *Johnson v. Ford Motor Co.*, 45 P.3d 86, 89 (Okla. 2002) (Each allegation of error not contained within argument in brief is waived). Moreover, "naked argument unsupported by facts or authority is without merit and will be treated as waived." *Tiger Flats v. Oklahoma Petroleum*, 711 P.2d 106, 108 (Okla. 1985).

A. WLC Waived Its Complaint About the Admission of Worldwide Sales Evidence Because WLC, Itself, Introduced Such Evidence.

Since WLC was the party who sought admission of the annual reports and shareholder statements containing the world-wide sales information, WLC cannot now complain that such evidence was inappropriate. *Ohler v. United States*, 529 U.S. 753, 756 (2000) ("a party introducing evidence cannot complain on appeal that the evidence was erroneously admitted"). Indeed, when WLC moved to admit these documents, it failed to seek redaction or admission for a limited purpose and cannot now complain of its own evidence. R. 3806, Tr. 2147-53.

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4. *See also* Okla. Sup. Ct. Rule 1.11(f): "The main contentions of the parties must be set forth in separate propositions. The argument and authorities in support of each proposition must follow the statement of the proposition . . ."

B. WLC Waived Its Objections to Jury Instructions by Not Raising Them in the Appellate Courts Below.

The essence of WLC's claims before this Court is that the jury received inappropriate or inadequate jury instructions during the punitive damage phase. The trial court instructed the jury according to the Oklahoma statute both as to the amount of damages that could be awarded and the factors that the jury could consider in awarding damages. For the first time before this Court, WLC now claims that the trial court committed numerous errors related to the punitive damages jury instructions including that the trial court "gave the jury a perfunctory instruction" and failed to give the jury any limitations (other than the Oklahoma Uniform Jury Instruction) on how it could calculate and award punitive damages. WLC further complains the trial court failed to properly define various statutory phrases including the "other persons or entities" language, for whom the financial benefit from harm could be calculated, or the geographic location of such other persons or entities. Pet. at 6.

WLC asserts that it requested certain jury instructions at the time of trial related to the punitive damages instructions. Pet. at 6. However, on appeal, WLC never presented any claim of error as to the punitive damage jury instructions to the Oklahoma courts below. Since WLC's challenges relate to definitions of phrases from the Oklahoma statute, it was incumbent upon WLC to present all arguments regarding the punitive damages instructions to the Oklahoma courts. Under Oklahoma procedural rules, any and all errors relating to jury instructions on punitive damages were waived by the failure to present the issue to the Courts of Oklahoma. Oklahoma Supreme Court Rule 15 requires a party complaining of an instruction given or refused to set out *in totidem verbis* the instruction or the portion thereof to which he objects together with his objection thereto. All "errors in refusing requested instructions or in giving

objectionable instructions are waived when not set out in compliance with this rule." *Avard v. Leming*, 889 P.2d 262, 266 (Okla. 1995). Indeed, the Oklahoma Supreme Court has stated that "Rule 15 contains no exceptions to its requirements . . ." *Ibid. See Howell v. Mississippi*, 125 S. Ct. 856 (2005) (*per curiam*) (writ dismissed as improvidently granted where petitioner failed to show that federal claim involving jury instruction was properly presented to state supreme court). In the instant case, WLC did not comply with Rule 15, and never allowed the Oklahoma courts to consider these potential points of error but now want this Court to be an appellate court of first review.

C. WLC Failed to Preserve Error on Its Challenges to the *BMW* and *State Farm* Factors.

To the extent WLC referred at all to *BMW* or *State Farm* in its initial Brief in Chief, it did so only in ***three*** sentences. That can hardly be sufficient to apprise the state courts of the nature of WLC's federal claims. This Court has previously held that "the discussion of a federal case in the midst of an unrelated argument, is insufficient to inform a state court that it has been presented with a claim." *Adams v. Robertson*, 520 U.S. 83, 88 (1997). Moreover, a ***three*** sentence argument would be insufficient to preserve any alleged error under Oklahoma procedural rules. *Oklahoma City Urban Renewal Authority v. City of Oklahoma City*, __ P.3d __, [Vol. #] WL 44399 (Okla. 2005) ("naked argument unsupported by facts or authority is without merit and will be treated as waived.") *quoting Tiger Flats v. Oklahoma Petroleum*, 711 P.2d 106, 108 (Okla. 1985). The Oklahoma Court of Civil Appeals expressed its frustration with WLC's obvious attempt at sandbagging by noting that that WLC failed to "specifically elucidate" how this case violated the principles of *BMW*.[5] In an abundance of caution, the

5. As discussed *supra*, WLC never made a challenge to the punitive damage award under of any of the *BMW v. Gore* "guideposts" in the courts below.

Court of Civil Appeals analyzed the award itself under all possible objections that WLC could have detailed (but chose not to) and stated that it did not find the punitive damage award grossly excessive under *BMW*. Pet. App. at 17.

D. WLC Waived Its Challenges to the Constitutionality of the Oklahoma Punitive Damages Statute.

In its state Petition for Certiorari, WLC failed to challenge the Oklahoma punitive damage statute as unconstitutional or specifically articulate the trial court's error and relied only upon broad policy arguments. *See Appendix.* All courts recognize a litigant's obligation to spell out its arguments "squarely and distinctly." *United States v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990) ("It is not enough merely to mention a possible argument in the most skeletal way, leaving the court to do counsel's work, create the ossature for the argument, and put flesh on its bones"). *See also Hardeman v. City of Albuquerque*, 377 F.3d 1106, 1122 (10th Cir. 2004) ("issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.").

For the first time before this Court WLC argues that the punitive damage statute 23 O.S. § 9.1 is unconstitutional because "on its face, the statute fails to provide juries and courts with standards sufficient to constrain them from making awards calculated on the basis of out-of state transactions." Pet. at 16. Nor did WLC preserve error regarding the court's jury instructions on this issue. Here WLC asks this Court to revisit the constitutional issues addressed in *BMW* and *State Farm*, even though such constitutional challenges were not fully and fairly presented to the courts below. Had WLC provided any substance at all to its constitutional argument, the Oklahoma courts could have addressed WLC's specific and detailed objections. WLC cannot sneak through the back door what it failed to present to state courts through the front.

II. The Opinion Below Withstands Scrutiny Under Both The *BMW* And The *State Farm* Analysis.

This Court explained in *BMW* and *State Farm* that the Fourteenth Amendment's Due Process Clause forbids the imposition of "grossly excessive" punitive damages by state courts. Courts reviewing punitive damages awards must therefore not only assess the nature and strength of state interests in deterring the conduct at issue, but also the proportionality of the damages in comparison to (1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages awarded; and (3) the difference between the punitive damages awarded and civil or criminal sanctions authorized or imposed in comparable cases. *State Farm*, 538 U.S. at 418; *BMW*, 538 U.S. at 568, 575.

WLC assails the Court of Civil Appeal's "perfunctory appellate decision" regarding the punitive damages issues and contends that the lower courts failed to analyze this case in light of the principles this Court established in *BMW* and *State Farm*. Pet. at 17. In truth, it was WLC that failed to adequately present or articulate its constitutional challenges to the courts below. The thrust of WLC's challenge to the punitive damage award was made on state law grounds. When the issue is properly raised, the Oklahoma Supreme Court has remitted punitive damages awards under the principles of *BMW*. *See Frank v. Mayberry*, 985 P.2d 773, 777 (Okla. 1999) ($200,000 damage award reduced to $50,000 in light of actual damage award of only $300). Importantly, this case was not even cited by the defendants in any of its briefing to the courts below.

Nevertheless, as outlined below, this punitive damage award is consistent with the principles of *BMW* and *State Farm*. Punitive damages may properly be imposed to further a State's legitimate interests in punishing unlawful conduct and deterring its repetition.

BMW, 517 U.S. at 568. Oklahoma has put in place a thoughtful, strict and appropriate statute to fulfill such interest and the jury in this case carefully applied it.

A. The Evidence of Increased Financial Benefit to WLC Justifies the Award.

WLC reasserts the argument made to the Oklahoma Court of Civil Appeals that there was a lack of evidence to support what financial benefit was derived by WLC from its wrongful conduct concerning Rezulin. The Oklahoma Court of Civil Appeals rejected this argument based upon its review of the actual evidence admitted at trial. WLC chose to not ask the Oklahoma Supreme Court to review that decision but now wants this Court to consider this argument anew.

Because Rezulin was first in its class, WLC was able to price the drug even higher than what was necessary to make a reasonable profit on the drug. In fact, WLC's Pricing Committee recommended a price for the drug that would have permitted a comfortable profit. R. 3806, Tr. 2093-94. Instead, senior management elected to market the drug at an even higher price than recommended by the Pricing Committee in order to further increase the company's profit margin. *Id.* So while other WLC drugs carried a profit margin of 15%, Rezulin's profit margin, as confirmed by the company's own internal documents, was as 31.7% for the year 1999. R. 3806, Tr. 2090-93; R. 3827, PX-1401, 2946. WLC documents also confirmed ***net*** Rezulin sales per month of $48 million. R. 3806, Tr. 2104; R. 3827, PX-2286. WLC states in its Petition that "there was no evidence of actual profits" even though Plaintiffs' exhibits 2946 and 2286 are WLC's own documents containing this exact evidence.

In the punitive damages phase, Wakefield's counsel referenced the annual shareholder reports introduced into evidence by WLC when discussing the increased financial benefit

to WLC. These documents, which included worldwide sales figures, coupled with the evidence discussed above, provided the jury with information that WLC's profits from Rezulin were over $600 million. WLC sold very little Rezulin outside of the United States of America because it only had the right to sell the drug in a handful of other countries (where the drug was approved for very limited use) resulting in miniscule sales. R. 3786, Tr. 440; R. 3793, Tr. 1407. Further, WLC's own expert testified that Oklahoma has the largest percentage number of diabetics of any other state in the country with close to 20% of the Oklahoma residents being susceptible to the disease. R. 3817, Tr. 3003. Just using simple math, with $600 million in profits, the jury had evidence before it that the Oklahoma sales alone exceeded $10 million. Due to the wide use of Rezulin in Oklahoma in light of that state's prevalence of diabetes, the jury could have inferred from the evidence at trial that a disproportionate share of Rezulin sales likely occurred in Oklahoma making such sales far in excess of $10 million.

B. The Jury Did Not Punish WLC for Otherwise Lawful Conduct.

Intentionally misrepresenting the risks and benefits of a prescription drug that then causes injury and death in order to induce sales is not legal in any state – a very different scenario from the *BMW* facts. Even WLC does not argue that the conduct assessed by this jury would be lawful in any other state. The Oklahoma Court of Civil Appeals correctly stated that the award in this case does not attempt "to sanction for conduct legal in other states." Pet. App. 18.

Further, the clear evidence at trial was that WLC's nationwide wrongful conduct including fraud and concealment of Rezulin's significant liver toxicity lead to the specific representations made to (and relied upon by) Oklahoma resident Michael Wakefield and his prescribing physician. The jury found

these representations to be intentionally fraudulent. Based upon WLC's false assurances of the drug's safety, Michael Wakefield was prescribed Rezulin which caused his death. All evidence of WLC's wrongdoing admitted at this trial was directly related to Michael Wakefield injury and death. *State Farm*, 538 U.S. at 1519. Unlike the *BMW* case, all of the admitted evidence had a direct impact on Oklahoma and its residents, including Michael Wakefield. *BMW*, 517 U.S. at 1597. WLC was punished by this jury for its intentional conduct that directly led to Michael Wakefield's death in Oklahoma. *State Farm*, 538 U.S. at 1521. The fact that precisely the same acts may have resulted in deaths in other states as well is irrelevant. WLC now asks this Court to significantly expand the Court's reasoning in *State Farm* and *BMW* to hold that because WLC itself introduced evidence at trial that showed its net worth, financial condition and worldwide sales, the punitive damage verdict is inappropriate and unconstitutional. R. 3826, DX 8001, 8002, 8003.

C. The Oklahoma Punitive Damages Award Statute Is Constitutional.

"A basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction." *State Farm*, 538 U.S. at 1523. Oklahoma did exactly this when it enacted 23 O.S. Supp. 2003 § 9.1. The statute provides clear and strict guidance to the trial courts as to how to instruct jurors on all factors that they may consider when awarding punitive damages. A jury may consider, *inter alia*, financial condition or net worth in order to assess an appropriate amount of punitive damages to set an example or punish a defendant. 23 O.S. Supp. 2003 § 9.1 (A) (7). To provide further protection against "multiple punitive damages awards for the same conduct," the statute requires a trial court to reduce any punitive damage award if the defendant has already paid

other punitive damage verdicts in the state of Oklahoma for the same conduct. *State Farm*, 538 U.S. at 1523; 23 O.S. Supp. 2003 § 9.1 (C) (2).

As explained above, the evidence in this trial did not relate to irrelevant "out-of-state misconduct." WLC's bad acts cut across state lines but came home to roost in Oklahoma. Moreover, considering global sales is wholly distinct from considering wrongful acts in other states. Whereas the former focuses on the impact of the award, the latter focuses on the particular acts being punished.

Finally, the trial court correctly instructed the jury on each factor to be considered in this award. There is no evidence to suggest the jury awarded damages based on any single factor – or piece of evidence – over any other. There is **NO** evidence in the record that the jury considered WLC's worldwide Rezulin sales for any inappropriate purpose – and WLC provides no proof or evidence of such. WLC does not cite to any evidence or argument of counsel that inappropriately asked the jury to consider dissimilar or unrelated lawful out-of-state conduct and punish WLC for such conduct through its punitive damage award. This is because no such evidence or argument exists. Rather the trial court limited the evidence to documents and testimony that related to the design and warnings of this drug as related to Michael Wakefield's use of Rezulin. Now, WLC asks this court to speculate that the jury ignored the court's instructions on the specific factors to consider when awarding punitive damages and instead used the documents introduced by WLC itself to inappropriately punish WLC for out-of-state conduct that was unrelated to the facts of this case. The Oklahoma Court of Civil Appeals summarily rejected this very same argument by WLC.

D. WLC Had Fair Notice of the Scope of Punitive Damage Exposure Because of Possible Civil or Criminal Penalties.

A company is entitled to "fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose." *State Farm*, 538 U.S. at 1520. States have "considerable flexibility in determining the level of punitive damages that they will allow." *BMW*, 517 U.S. at 568. One factor that assists in the concept of fair notice is the civil or criminal penalties "that could be imposed for comparable misconduct." *BMW*, 517 U.S. at 583; *State Farm*, 538 U.S. at 1526. Corporations doing business in Oklahoma have fair notice of Oklahoma's possible penalties from the punitive damages statute itself which permits punishment up to the "increased financial benefit" derived from intentional, wrongful and malicious conduct. 23 O.S. Supp. 2003 § 9.1(C)(2)(c). Additionally under 78 OKLA. STAT. § 54, the attorney general, on behalf of Oklahoma consumers, can divest a corporation of all money received by a wrongdoer who engages in deceptive acts in Oklahoma. Deceptive acts include, "knowingly mak[ing] a false representation as to the characteristics . . . benefits . . . of goods or services. 78 OKLA. STAT. § 54(A)(5). Oklahoma has full authority to punish a wrongdoer by divesting that wrongdoer of profits or earnings derived from such wrongful conduct.

As for comparable criminal penalties, WLC is well aware that there are financial ramifications in the criminal context for drug companies that falsify data or conceal study data. Indeed, in 1995, WLC pled guilty to a felony conviction for intentionally concealing study data on another prescription drug and was fined $10 million for such conduct. R. 3780, Tr. 103-08. The jury's award of punitive damages in this case was right in line with WLC's knowledge of the consequences for this type of conduct.

E. The Closest and Most Analogous Case Supports the Jury Award.

In a very similar defective drug case, American Home Products (AHP) made almost identical arguments to those asserted here to the Oregon Court of Appeals when punitive damages were awarded against that company for failing to properly warn about the vision loss side effects of a prescription drug, Cordarone. *Axen v. American Home Products Corporation*, 158 Or. App. 292, 974 P.2d 224 (Or. App. 1999), *cert. denied*, 528 U.S. 1136. The evidence of reprehensibility in that case was far less compelling than the evidence here but did include evidence that AHP deliberately placed misleading information on its packaging in order to promote sales. *Id.* at 320.

As to AHP's argument that the jury's punitive award constituted an attempt by Oregon to impose its regulatory policies on the rest of the country and to punish AHP for lawful and uncharged conduct, the *Axen* Court affirmed the punitive award after going through the exact analysis articulated here by Wakefield. The court held that the company was:

> not punished for its promotional activities outside of Oregon – it was punished for failing to warn Douglas Axen's physicians that the [drug] was associated with optic neuropathy and vision loss. As a consequence of that failure to warn, Cordarone was prescribed to Douglas Axen in Oregon and was purchased and taken by him in Oregon. Douglas Axen' use of Cordarone ultimately led to his vision loss, again in Oregon. Any information submitted to the jury about [the drug company's] promotional practices was for the purpose of determining the egregiousness of [the drug company's] activities within Oregon, not as further grounds for punishment.

Axen at 240. In this case, the Oklahoma Court of Civil Appeals faced these same arguments and also affirmed the punitive award as

it "neither reflects a grossly excessive award, nor attempts to sanction Manufacturing Defendants for conduct legal in other states." Pet. App. 18.

F. The Evidence of WLC's Reprehensibility Justifies the Jury Award.

When judging the reasonableness of a punitive damages award, the court's most important indicium is the degree of reprehensibility of the wrongdoer. *BMW*, 517 U.S. at 575. Most of the factors of reprehensibility identified in *State Farm* are present in this case: (1) the harm caused was severe physical injury leading to death, rather than mere economic damage; (2) WLC's repeated misrepresentations and intentional concealment of data showed reckless disregard to public health and safety; (3) the jury heard evidence of more than two dozen incidents of wrongdoing and fraud showing a pattern of repeated actions which conduct directly caused Wakefield's death and (4) Michael Wakefield's death was the result of WLC's intentional malice and conscious deceit. *See Rhone-Poulenc Agro S.A. v. DeKalb Genetics Corp.*, 345 F.3d 1366, 1371 (Fed. Cir. 2003) *cert denied*, 540 U.S. 1183 (jury finding of intentional malice, trickery or deceit satisfies *BMW's* requirement of reprehensibility). WLC has not preserved any points of error on this issue and has accepted the jury's judgment on its conduct.

III. The Jury Award Is Not Grossly Excessive Under *State Farm* Standards.

Only when an award can "fairly be categorized as 'grossly excessive' in relation to [the state's] interests does it enter the zone of arbitrariness that violates the Due Process Clause of the Fourteenth Amendment." *BMW*, 517 U.S. at 568. This Court in *BMW* "rejected the notion that the constitutional line is marked by a simple mathematical formula," but further stated that a ratio of 10 to 1 may be relevant and appropriate. *BMW*, 517 U.S. at

582. "Single digit multipliers are more likely to comport with due process, while still achieving the State's goals of deterrence and retribution." *State Farm*, 538 U.S. at 1524. During the punitive damages stage, Wakefield's counsel suggested to the jury that it consider a range for a punitive award between $21 million (representing WLC's increased financial benefit only for the days that Wakefield took the drug) and $600 million (representing WLC's profit from sales of Rezulin). R. 3823, Tr. 3410. The actual punitive verdict was substantially below the lowest recommended range and calculated by the jury themselves at just over six times the actual damages awarded. Certainly a punitive damage award of $10 million for the tragic death of a man whose loss of wages alone were shown to be $5 million is not "grossly out of proportion to the severity of the offense." *BMW*, 517 U.S. at 576.

Further, this Court has suggested the potential propriety of maximum multipliers for punitive damages only for cases limited to economic damages. In both *State Farm* and *BMW*, the Court indicated that the economic nature of the damages was a significant factor in its decisions. *State Farm*, 538 U.S. at 1525; *BMW*, 517 U.S. at 580-81. This Court has never suggested that such maximums should apply to wrongful conduct that severely injures or kills. Certainly different limitations on punitive damages may be appropriate in cases like this, in which the defendant intentionally engaged in conduct that they knew could be fatal and actually caused a human being to die a horrible, slow and painful death. The injury involved in this wrongful death case is a far cry from the economic or mental anguish injuries involved in the cases on which WLC relies.

CONCLUSION

For the foregoing reasons, the Petition for a Writ of Certiorari should be denied.

Respectfully submitted,

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APPENDIX

APPENDIX — EXCERPT FROM WLC'S PETITION FOR CERTIORARI TO THE OKLAHOMA SUPREME COURT

* * *

IV. THE COCA AFFIRMED THE PUNITIVE DAMAGE AWARD CONTRARY TO U.S. SUPREME COURT AUTHORITY

The COCA held that, in determining punitive damages, the jury could properly consider Warner-Lambert's profits from *worldwide* sales of Rezulin, not just sales of Rezulin that caused injury in Oklahoma. Opinion at 18-20. This holding (1) squarely conflicts with U.S. Supreme Court decisions, and (2) presents important questions never determined by this Court.

In *BMW of North America v. Gore*, 517 U.S. 559, 574 (1996), the Supreme Court ruled that, under the U.S. Constitution, "the scope of the interest in punishment and deterrence that a [state] court may appropriately consider is properly limited" to the interests of that state's citizens, "rather than those of the entire Nation." *Id.* at 574. The COCA understood this to mean only that "states may not impose economic sanctions on violators of its law with the intent of changing tort-feasors' *lawful* conduct in other states," and upheld the punitive damage award because it did not "attempt[] to sanction Manufacturing Defendants for conduct *legal in other states.*" Opinion at 19-20 (emphasis added). The COCA ignored the U.S. Supreme Court's contrary holding that punitive damages may not be imposed to punish out-of-state conduct *regardless* of whether that conduct would be considered lawful or unlawful where it occurred:

> "A State cannot punish a defendant for conduct that may have been lawful where it occurred. . . .

> *Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction.*"

State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408, 421 (2003) (emphasis added). *Accord*, *Continental Trend Resources, Inc. v. OXY USA Inc.*, 101 F.3d 634, 637 (10th Cir. 1996) ("[A]ny penalty must be supported by Oklahoma's 'interest in protecting its own consumers and its own economy.' . . . [W]e read the opinion [in *Gore*] to prohibit reliance upon inhibiting unlawful conduct in other states"), *cert. denied*, 520 U.S. 1241 (1997).

The COCA decision also raises important questions not yet addressed by this Court regarding 23 O.S. Supp. 2003, § 9.1(C), which limits punitive damages to "the increased financial benefit derived by the defendant as a direct result of the conduct that caused injury to the plaintiff and other persons or entities." This Court has never adopted the COCA's position that "conduct that caused injury" includes conduct that caused injury to people outside Oklahoma, which runs afoul of the holding in *State Farm.* Indeed, given the requirement of 23 O. S. Supp. 2003, § 9.1 (C) that punitive damage awards be reduced only by punitive damage verdicts entered in *Oklahoma* courts, the adjacent statutory language referring to "injury to the plaintiff and other persons or entities" must mean injury in Oklahoma.

Moreover, by measuring "increased financial benefit" by total sales – including sales that did *not* cause any injury – the COCA ignored the restriction that punitive damages must be limited to the financial benefit "derived . . . as a direct result of the conduct that caused injury." This Court has never

adopted the COCA's position that "conduct that caused ***injury***" (emphasis added) includes conduct that did ***not*** cause any injury, such as sales of Rezulin to the vast majority of people who benefitted greatly from the drug and had no ill effects. *See In re Rezulin Prod. Liab. Lit.*, 210 F.R.D. 61, 66 n.37 (S.D.N.Y. 2002) (even plaintiffs' experts admit that "Rezulin was effective for 95 percent of the patients who ingested it"). The Constitution does not permit a punitive damage award based on "conduct that bore no relation to the [plaintiff's] harm." *State Farm*, 538 U.S. at 422.

Finally, the $10 million punitive award (seven-fold the compensatory award) is so excessive as to require this Court's exercise of its supervisory power. In *State Farm*, 538 U.S. at 425, the Supreme Court reiterated that "an award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety," and stated that "[w]hen compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee." *See Chandler v. Denton* 1987 OK 38, ¶ 30, 741 P.2d 855, 868 ("In light of the generously and amply compensated loss for Chandler's actual harm, we find the exemplary damages allowed by the jury not to be responsive to the purpose of civil punishment."). That is exactly the case here.

* * * *

(3)
Supreme Court, U.S.
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No. 04-1047

In The Supreme Court of the United States

WARNER-LAMBERT COMPANY and PFIZER INC.,

Petitioners,

v.

MARY ROSE WAKEFIELD, INDIVIDUALLY, AS PERSONAL REPRESENTATIVE, TRUSTEE, EXECUTOR OF THE ESTATE OF MICHAEL HOLMES WAKEFIELD AND MARY LOUISE WAKEFIELD,

Respondent.

On Petition For Writ Of Certiorari To The Oklahoma Court Of Civil Appeals

REPLY ON PETITION FOR A WRIT OF CERTIORARI

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PRELIMINARY STATEMENT

Respondent's Brief in Opposition ("R. Br.") virtually ignores the reasons for granting certiorari. Instead, respondent devotes almost all of her brief to arguing that certain questions – but not the specific Questions Presented – were not preserved. As shown in Point III, *infra*, the Questions Presented were raised in and specifically addressed by the court below, and the points in the petition are all "fairly included" within those questions. Sup. Ct. R. 14.1(a). What little argument respondent offers on the issue of whether certiorari should be granted does not refute petitioners' showing that the punitive damages were calculated on the basis of world-wide sales and profits from an FDA-approved drug, which squarely conflicts with *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003), and *BMW of North America v. Gore*, 517 U.S. 559 (1996), and presents significant issues for this Court's review.

As discussed in the petition and in the *amicus* briefs submitted in support thereof, the context for the Questions Presented is that a jury was instructed by counsel and permitted to calculate punitive damages regarding a prescription drug on the basis of worldwide sales figures, when those sales were lawful because the drug was approved for sale by the FDA and foreign regulatory agencies. That result creates a risk of excessive, multiple punishments based on out-of-state conduct. Moreover, that conduct lacks the requisite "nexus" to any harm to this plaintiff and has no relationship to reprehensibility, because worldwide sales necessarily include sales to everyone who benefitted from the drug and did not sustain any harm. That result also allows a jury to become a *de facto* national regulator of what prescription drugs may be sold nationally, contrary to this Court's holding that a state may not "use the punitive damages deterrent as a means of imposing its regulatory policies on the entire Nation." *BMW*, 517 U.S. at 585. That power undermines the FDA's expert determination that a drug should be on

the market because its benefits outweigh its risks, and chills the incentive to develop vitally needed medications, adversely affecting health care. Respondent's brief simply ignores these and other important legal and policy considerations, which flow from *BMW* and *State Farm*. In addition, this petition is an ideal vehicle for this Court to examine the holdings of these two landmark decisions in a product liability/personal injury case, because plaintiff argues that those cases apply only where economic injury was claimed.

ARGUMENT

I. RESPONDENT ADMITS THAT THE JURY WAS TOLD TO CALCULATE PUNITIVE DAMAGES ON THE BASIS OF WORLDWIDE REZULIN SALES AND PROFITS, AND THE HOLDING OF THE COURT BELOW THAT THIS CALCULATION IS CONSISTENT WITH *BMW* AND *STATE FARM* UNDERSCORES THE NEED FOR CERTIORARI

The ***only*** "evidentiary support for the award of punitive damages" identified by the Oklahoma Court of Civil Appeals was "evidence of the dollar amount of world-wide gross sales of Rezulin – $48 million per month," and alleged "expert testimony that [Warner-Lambert's] profit margin on Rezulin sales was thirty percent." App. 17. Such profits, the court held, "clearly provided a basis for jury determination" under the Oklahoma punitive damages statute, 23 OKLA. STAT. § 9.1(C), of "the increased financial benefit derived by the defendant as a direct result of the conduct causing the injury to the plaintiff and other persons or entities." *Id.* Thus, the highest state appellate court to hear this case expressly found that the punitive damage award was based on worldwide sales and profits. That disposes of respondent's assertion that petitioners are asking the Court to "speculate" about the basis for the award. R. Br. at 4.

This punitive damage award is directly contrary to *State Farm* and *BMW*. In *BMW*, 517 U.S. at 572-73, the Court held that a State "does not have the power . . . to punish [a defendant] for conduct that was lawful where it occurred and that had no impact on [that State] or its residents." Respondent had the burden of showing that the out-of-state conduct was unlawful. *Id.* at 573. But there was no evidence as to the law of any other state, and the jury was not asked to apply such law. Thus, there was no basis on which the jury could have found that all of the worldwide sales of Rezulin were unlawful. Nor does respondent even argue that they were. By upholding punitive damages calculated on the basis of worldwide sales and profits, the courts below improperly punished petitioners for conduct – selling Rezulin – that was "lawful where it occurred" and "had no impact on [Oklahoma] or its residents." *Id.* at 572-73.

The court below held that the award does not punish defendants "for conduct legal in other states." A. 18. Indeed, respondent asserts that Warner-Lambert's conduct was "not legal in any state." R. Br. at 23. A grant of the petition is warranted to clarify and re-affirm this Court's holding that states have no "legitimate concern in imposing punitive damages to punish a defendant" even for "unlawful acts committed outside of the state's jurisdiction. . . . [E]ach State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction." *State Farm*, 538 U.S. at 421-22. *Axen v. American Home Prod. Corp.*, 158 Or. App. 292, 316, 974 P.2d 224, 240 (1999), on which respondent relies, is not to the contrary, because the punitive award in that case was not calculated on out-of-state sales.

Worldwide sales, which include sales to every diabetic who benefitted from and had no complications from Rezulin treatment, also have no "nexus to the specific harm suffered by the plaintiff," as required by *State Farm*, 538 U.S. at 422. No such nexus was identified by the court below. Respondent ignores the argument.

Moreover, basing a punitive award on worldwide sales violates the Due Process Clause prohibition against "arbitrary punishments" (*id.* at 409), for the reasons explained in the Petition at 21-22. Respondent ignores the issue. Contrary to *BMW*, 517 U.S. at 574, petitioners had no "fair notice" that this arbitrary factor could be used to calculate punitive damages. No such notice is provided by 23 OKLA. STAT. § 9.1(C), because worldwide sales have no relationship to any "increased financial benefit" derived "as a direct result of the conduct causing the injury." As respondent correctly states, "global sales" are "wholly distinct" from "wrongful acts in other states." R. Br. at 25. Yet, punitive damages in this case were improperly assessed on the basis of global sales and purported profits.

Petitioners were further denied due process because there was no evidence of the actual profit margin for Rezulin while it was on the market, and accordingly there was no basis for any finding of "financial benefit" to Warner-Lambert "as a direct result of the conduct causing the injury." Respondent's assertion that Rezulin had a 31.7% profit margin in 1999 is false. R. Br. at 22.[1] Nor could the jury "infer" the amount of Rezulin profits from Oklahoma (R. Br. at 23) when there was no evidence of sales, profits, or prescriptions in Oklahoma.

Respondent's argument that the punitive award is justified in light of Warner-Lambert's alleged "misdeeds" and "reprehensibility" (R. Br. at 3, 28) further illustrates the need to clarify and re-emphasize this Court's decisions. *State Farm* held that "[d]ue process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant

[1] Exhibit 2946, cited by respondent, was specifically identified at trial as a "forecast for sales and profitability" that "projected" profit margins, and therefore is not evidence of actual profits. Respondent correctly states that Exhibit 2286 shows that Rezulin had $48.7 million "net sales" in January 1998, but does not mention the testimony that net sales are simply "sales less rebates and discounts," not profits. R.3806, Tr. 2104.

under the guise of [a] reprehensibility analysis." 538 U.S. at 423. Nevertheless, many state courts have used a "reprehensibility analysis" to approve punitive damages based on out-of-state conduct, nullifying that principle.[2]

Respondent's argument that the jury could properly consider Warner-Lambert's "net worth" or "financial condition" in assessing punitive damages misstates the basis for the award. R. Br. at 4-5, 24. In summation, respondent's counsel did not ask the jury to award punitive damages based on net worth or financial condition, but on alleged profits from worldwide Rezulin sales, in a range of $21-$600 million. R.3823, Tr. 3410. Respondent concedes that her counsel made this argument. R. Br. at 29. And this was the sole "evidentiary support" for the calculation of punitive damages found by the Court of Civil Appeals. A. 17.

Respondent argues that evidence of worldwide Rezulin sales came from Warner-Lambert's annual reports that defendants offered at trial. R. Br. at 2. But the fact that evidence is properly admitted does not mean that it can be used for an unconstitutional purpose. The only reference at trial to the sales figures in the annual reports was by respondent's counsel during her summation in the punitive damages phase.

Respondent says that there is no conflict among lower courts, so that petitioners "merely" argue that the decision below conflicts with U.S. Supreme Court authority. R. Br.

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[2] *See, e.g.*, *Boeken v. Philip Morris, Inc.*, 2005 WL 737511, at *32-42 (Cal. Ct. App. April 1, 2005) (upholding punitive damages of $50 million, a 9:1 ratio, based on out-of-state conduct); *Williams v. Philip Morris, Inc.*, 193 Or. App. 527, 559 n.8, 92 P.3d 126, 143 n.8, *review granted*, 337 Or. 669, 104 P.3d 601 (2004) (court upheld punitive award in a 96:1 ratio by holding that "all of the out-of-state conduct . . . led to actions within Oregon or that were directed to Oregonians [so] Oregon has the authority to punish defendant for such conduct"); *Craig v. Holsey*, 590 S.E.2d 742 (Ga. Ct. App. 2003) (using reprehensibility analysis to uphold a 22:1 ratio); *Bocci v. Key Pharm., Inc.*, 76 P.3d 669, 674 (Or. Ct. App. 2003) (using same analysis to uphold a 7:1 ratio).

at 5. But that decision and the state court cases cited in n.2, *supra*, do conflict with appellate decisions that conform to *State Farm* and *BMW*. *See, e.g., White v. Ford Motor Co.*, 312 F.3d 998, 1020 (9th Cir. 2002); *Continental Trend Resources, Inc. v. OXY USA Inc.*, 101 F.3d 634, 637 (10th Cir. 1996), *cert. denied*, 520 U.S. 1241 (1997). That is yet another reason why certiorari should be granted. Notably, contrary to respondent's assertion that only a "small fraction" of cases involving Rezulin remain (R. Br. at 6), thousands of such cases are still pending in the federal MDL court and various state courts, so these issues could arise again in the same context.

II. THE PUNITIVE DAMAGE AWARD IS UNCONSTITUTIONALLY EXCESSIVE

Respondent argues that *State Farm* and *BMW* are limited to cases involving economic damages. But this Court has not said that, and in numerous product liability cases involving physical harm it granted certiorari, vacated the punitive damages judgment, and remanded for reconsideration in light of *State Farm*.[3] Moreover, lower courts have applied *State Farm* and *BMW* to punitive damage awards in personal injury/product liability cases. *See, e.g., Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594, 602-03 (8th Cir. 2005) (reducing punitive damages in product liability case to a 1:1 ratio, based upon *State Farm* and *BMW* analysis). To the extent that the Oklahoma Court of Civil Appeals and other courts might accept respondent's contention that *State Farm* and *BMW* are inapplicable to personal injury cases, that is another reason for granting certiorari.

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[3] *See Philip Morris USA, Inc. v. Williams*, 504 U.S. 801 (2003); *Key Pharms., Inc. v. Edwards*, 538 U.S. 974 (2003); *Anchor Hocking, Inc. v. Waddill*, 538 U.S. 974 (2003); *Ford Motor Co. v. Romo*, 538 U.S. 1028 (2003).

Respondent's argument that the punitive damage award was not unconstitutionally excessive because "it was substantially below the lowest recommended range" is specious. R. Br. at 29. That "recommendation" was made to the jury by respondent's counsel, and ranged from $21 million to $600 million, which in itself demonstrates the unprincipled nature of the basis on which the jury was told to calculate punitive damages. By the same reasoning, any punitive damage award would pass muster so long as it was lower than the top of some outrageous range requested by the plaintiff's counsel.

III. PETITIONERS' ARGUMENTS WERE PRESERVED

Respondent's argument that Warner-Lambert failed to preserve its claims of error is frivolous. The first Question Presented is whether the punitive damage award conflicts with *State Farm* and *BMW*. *See* Petition at i. Petitioners made this precise argument at every stage of the proceedings below. *See id.* at 7. And the argument was not made in only "three sentences," as respondent suggests (R. Br. at 19), but in numerous pages in petitioners' "Brief in Chief" (opening brief) and reply brief to the Oklahoma Court of Civil Appeals. Petitioners specifically argued that the punitive damage award was unconstitutional because it was based on worldwide sales and had no nexus to any harm to the plaintiff. *See* Appellants' Brief in Chief at 26-29 and Reply Brief at 22-29. *State Farm* was mentioned five times in petitioners' Brief in Chief and 14 times in the reply brief. *BMW* was mentioned twice in the Brief in Chief and once on reply.

Respondent admits that the Court of Civil Appeals "addressed [Warner-Lambert's] arguments under *State Farm* that there was an 'insufficient nexus between the punitive damages and the actual harm suffered by plaintiff,'" and also "addressed [Warner-Lambert's] argument that the award violated the guidelines outlined in *BMW*." R. Br. at 15. "Where the court below actually passes on a

federal question, any inquiry into whether or when the question was raised for jurisdictional purposes becomes irrelevant." *Jenkins v. Georgia*, 418 U.S. 153, 157 (1974); *Raley v. Ohio*, 360 U.S. 423, 436-37 (1959). Respondent does not even argue that the second Question Presented (whether the award is unconstitutionally excessive) was not preserved. Nor did respondent argue below that the punitive damages issues were not preserved. Thus, "the record as a whole" shows that the Questions Presented were "adequately presented in the state system." *Board of Dir. of Rotary Int'l v. Rotary Club of Duarte*, 481 U.S. 537, 549-50 (1987).

Respondent cites Oklahoma cases stating that points of error not contained in appellate briefs are waived. But in each case, the appellant neither made any argument on the claim of error nor cited any authority.[4] In contrast, petitioners extensively briefed the punitive damages issues, based on *BMW* and *State Farm,* in both of their briefs to the Court of Civil Appeals.

Petitioners also asked the Oklahoma Supreme Court to review these issues. Petitioners' Brief in Chief was initially filed with the Supreme Court, which then decided to refer the case to the Court of Civil Appeals. Recognizing that the Supreme Court has already seen the Brief in

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[4] *Oklahoma City Urban Renewal Auth. v. City of Oklahoma City*, ___ P.3d ___, 2005 WL 44399 (Okla. Jan. 11, 2005) (claim of error not briefed); *Johnson v. Ford Motor Co.*, 45 P.3d 86 (Okla. 2002) (nine points of error asserted, but only three briefed); *Tiger Flats Prod. Co. v. Oklahoma Petroleum*, 711 P.2d 106 (Okla. 1985) (claim of error merely alluded to in briefs, without supporting authority); *Peters v. Golden Oil Co.*, 600 P.2d 330 (Okla. 1979) (appellant cited no authority and made no argument to convince appellate court to reverse); *Hardeman v. City of Albuquerque*, 377 F.3d 1106 (10th Cir. 2004) (appellants indicated in their post-trial motion that they were *not* seeking review of a constitutional issue, and thus failed to preserve it); *U.S. v. Zannino*, 895 F.2d 1 (1st Cir.), *cert. denied*, 494 U.S. 1082 (1990) (appellant attempted to "adopt" arguments of co-defendants in brief without providing any argument of his own).

Chief, the certiorari process in Oklahoma does not provide for full briefing, but rather for a limited 10-page petition for certiorari. Okla. Sup. Ct. R. 1.179(b). By rule, "[t]he petition, answer, and reply shall not reach the merits of the appeal." Okla. Sup. Ct. Rule 1.179(d).

Respondent argues that petitioners waived their argument that the trial court refused their requested instructions based on *BMW*, 517 U.S. at 572-73, to limit the jury's focus to Oklahoma transactions. Respondent ignores U.S. Supreme Court Rule 14.1(a), which provides that "[t]he statement of any question presented is deemed to comprise every subsidiary question fairly included therein." Under this rule, "[o]nce a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below." *Harris Trust and Sav. Bank v. Salomon Smith Barney, Inc.*, 530 U.S. 238, 245 n.2 (2000). Respondent admits that after the trial court delivered its instructions to the jury, her counsel asked the jury to calculate punitive damages based on the global profits for Rezulin, triggering the constitutional issue. R. Br. at 29. The trial court's refusal to give instructions, based on *BMW*, that it could not award punitive damages based on out-of-state conduct that had no relationship to any harm to the plaintiff is part of the procedural history "fairly included" in the first Question Presented.[5]

Contrary to respondent's argument (R. Br. at 20), petitioners are not contending that the Oklahoma punitive damages statute is unconstitutional on its face, but that it was "interpreted and applied" in an unconstitutional manner. Petition at 16. Petitioners argued in their Brief in Chief (at 27) that the statute should be interpreted as

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[5] *Howell v. Mississippi*, 125 S. Ct. 856, 858 (2005), cited by respondent, is distinguishable because the petitioner "did not properly present his claim" before the state appellate court "as one arising under federal law." Petitioner also cites Oklahoma Supreme Court Rule 15, but that was repealed in 1997.

limited to financial benefit in Oklahoma that has a nexus to harm to this plaintiff. But the Court of Civil Appeals held that the statute could encompass "world-wide gross sales." A. 17. Under that interpretation, the statute is unconstitutional in light of *BMW* and *State Farm*. That issue arose only after the Court of Civil Appeals failed to interpret the statute in a constitutional manner. Petitioners then raised the issue in their certiorari petition to the Oklahoma Supreme Court. R. Br. at 2a.

CONCLUSION

For the foregoing reasons, and the reasons set forth in the petition, the petition for a writ of certiorari should be granted.

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IN THE

Supreme Court of the United States

WARNER-LAMBERT CO., *et al.*,

Petitioners,

v.

MARY ROSE WAKEFIELD,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE OKLAHOMA COURT OF CIVIL APPEALS

MOTION OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND BUSINESS ROUNDTABLE FOR LEAVE TO FILE A BRIEF AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS AND BRIEF *AMICI CURIAE*

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The Chamber of Commerce of the United States of America (the "Chamber") and Business Roundtable (the "Roundtable") hereby move pursuant to Supreme Court Rule 37.2(b) for leave to file the attached *amici curiae* brief in support of Warner-Lambert Company's and Pfizer Inc.'s petition for a writ of certiorari to the Oklahoma Court of Civil Appeals. *Amici* are filing this motion because consent to the filing of this brief was granted by counsel for Petitioners but denied by counsel for Respondent.

The Chamber is the nation's largest federation of business companies and associations, with an underlying membership of more than 3,000,000 businesses and professional organizations of every size and in every sector and geographic region of the country. Because the fair administration of punitive damages long has been a concern of the business community, the Chamber regularly files *amicus* briefs in punitive damages cases. It is the Chamber's experience that the lower courts routinely have been misapplying and effectively nullifying the principles identified by this Court in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and clarified in *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003).

The Roundtable is an association of the chief executive officers of approximately 150 member companies with a combined workforce of more than 10 million employees in the United States and about $4 trillion in revenues. The executives who created the Roundtable believed that the U.S. economy would be healthier, there would be less unwarranted intrusion by government into business affairs, and the interest of the public would be better served if the business sector were to play an active and effective role in public affairs. The Roundtable's participation as *amicus* is consistent with its overall goal of representing the views of its membership before all branches of government on important matters affecting the business sector.

Amici are concerned that the Oklahoma Court of Civil Appeal's approval of a $10 million punitive damages award against the manufacturer of a nationally distributed, federally regulated and approved product exemplifies the continued, erroneous application of *Gore* and *State Farm* in the critically important field of products liability law, not only because the lower court completely abdicated its responsibility to prevent the assessment of punitive damages based on out-of-state conduct that was beyond the constitutional authority of Oklahoma to regulate, but because the lower court failed to perform the searching scrutiny required to ensure that a jury-imposed sanction comports with due process limitations on proportionality. *Amici* are uniquely positioned to assist the Court in this case because their members are subject to, and directly affected by, a tort system that threatens manufacturers and sellers of federally regulated and nationally distributed products with ruinous liability, and they have a fundamental interest in the articulation and enforcement of rules that promote reasoned and properly guided decision-making by judges and juries alike.

Accordingly, the Chamber and the Roundtable respectfully request that this Court grant leave to file the attached *amici curiae* brief.

Respectfully submitted,

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INTEREST OF *AMICI CURIAE*

The Chamber of Commerce of the United States of America (the "Chamber") is the nation's largest federation of business companies and associations, with an underlying membership of more than 3,000,000 businesses and professional organizations of every size and in every sector and geographic region of the country.[1] Because the fair administration of punitive damages long has been a concern of the business community, the Chamber regularly files *amicus* briefs in punitive damages cases.

The Business Roundtable (the "Roundtable") is an association of the chief executive officers of approximately 150 member companies with a combined workforce of more than 10 million employees in the United States and about $4 trillion in revenues. The executives who created the Roundtable believed that the U.S. economy would be healthier, there would be less unwarranted intrusion by government into business affairs, and the interest of the public would be better served if the business sector were to play an active and effective role in public affairs. The Roundtable's participation as *amicus* is consistent with its overall goal of representing the views of its membership before all branches of government on important matters affecting the business sector.

Amici have a particular concern with widespread and growing efforts to impose punitive damages in products liability cases involving nationally distributed products based on a manufacturer's single design or labeling decision (or similar course of action) which is alleged to have affected all end users indiscriminately. These efforts threaten massive and potentially crippling punitive damage impositions as individual juries are

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[1] A motion for leave to file an *amici curiae* brief is attached hereto. Pursuant to Supreme Court Rule 37.6, *amici curiae* declare that no counsel for any party to this case authored this brief in whole or in part and that no entity or person, other than *amicus* the Chamber, its members, and its counsel, made any monetary contribution to the preparation or submission of this brief.

repeatedly requested not only to "punish and deter" the same alleged misconduct, but to assess punitive awards based in whole or in part on the totality of alleged injury caused by that misconduct. If unchecked, the mere threat of such overlapping punitive damages awards violates Constitutional due process standards by impairing defendants' positions in financial markets and compromising their ability to defend even before liability is adjudicated. In the current punitive damages environment, unproven allegations that a product is implicated in a mass tort are enough to cause severe economic disruption for the manufacturer, pushing down stock prices, disrupting contractual relationships with third parties, and raising borrowing costs.

In *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996) and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), this Court articulated due process guideposts and limitations on punitive damages awards, including extraterritoriality limitations, which have somewhat ameliorated the problem presented by runaway punitive damages. It is *amici*'s experience, however, that state reviewing courts often have misapplied and effectively nullified the *Gore* and *State Farm* principles.[2] Indeed, on appeal from the trial court's judgment, Respondent appears to have succeeded in persuading the Oklahoma Court of Civil Appeals that the principles announced in *Gore* and *State Farm* should be limited to the unique facts of those cases. Thus, *amici* seek to have this Court reinforce the *Gore* and *State Farm* principles and to give additional consideration to their specific adaptation in the context of products liability cases, with particular attention to the substantial potential that punitive damages awarded in such

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[2] See Appellees' Brief in Response at 27, *Wakefield v. Warner-Lambert Co.*, No. 99,086 (Okla. Dec. 29, 2003) (arguing that "*Gore* . . . only applies to illegal conduct that resulted in a *purely economic* injury" and *State Farm* "does not apply . . . because the [extraterritorial] conduct penalized in that case bore no relation to the Campbells' claims in particular" (emphasis in original)).

cases will not only raise excessiveness concerns but unduly burden interstate commerce.

REASONS FOR GRANTING THE PETITION

This case provides a paradigmatic vehicle for addressing the issues raised by punitive damages in products liability cases. It involves a product, Rezulin®, which was distributed nationally by Petitioner Warner-Lambert Company under uniform design specifications and labeling approved, as required by federal law, by the Federal Food and Drug Administration ("FDA").[3] Notwithstanding that approval, Respondent (plaintiff below) was permitted to challenge both the propriety of Warner-Lambert's distribution of the product and the adequacy of Warner-Lambert's labeling under Oklahoma's general tort law standards. The jury was allowed to assess whether Petitioners' interactions with the FDA in securing marketing approval warranted an imposition of punitive damages. The jury was further permitted by Oklahoma law and urged by Respondent's counsel to assess punitive damages based on Petitioners' alleged worldwide profits from sales of Rezulin®. The $10 million punitive award was indisputably based on these worldwide profits.

As shown below, the award clearly violated the territoriality teachings of *Gore* and *State Farm* by sanctioning Petitioners' sales activity outside Oklahoma without any finding that such conduct was unlawful under the law of any other jurisdiction. In addition, the award does not foreclose the pursuit of similar awards based on the same conduct and the same alleged profits by the many plaintiffs claiming Rezulin® injury in other States. The jury's $10 million punitive sanction, approximately 6.5 times the jury's $1.55 million compensatory award, thus raises issues of excessiveness under the standards set forth in *Gore* and *State Farm*, as well as substantial, related questions of cumulative burden on interstate commerce.

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[3] Petitioner Warner-Lambert Co. is a wholly owned subsidiary of Petitioner Pfizer Inc.

It is vitally important that the Court clarify that lower courts cannot endorse the imposition of multiple, excessive, and duplicative sanctions arising out of the design and marketing of nationally regulated and distributed products without any regard to whether the defendant's conduct (1) is unlawful in other jurisdictions; or (2) has been (or should have been) punished previously.[4] Accordingly, the petition for certiorari should be granted to provide essential guidance on the proper application of *Gore* and *State Farm* in the products liability field.

I. Certiorari Should Be Granted Because The Lower Court Flouted This Court's Rulings By Affirming A $10 Million Punitive Damages Award That Considered Out-Of-State Sales Absent Any Showing That Such Sales Were Unlawful

The lower court's affirmance of a $10 million punitive damages award based on out-of-state sales of Warner-Lambert's FDA-approved drug Rezulin® squarely contravenes this Court's holdings in *Gore* and *State Farm*.

At the liability phase of the trial, there was no evidence that Warner-Lambert's conduct was motivated by personal *animus* or otherwise specifically directed to the injured party. Instead, the jury was presented with evidence bearing on the inherent qualities of the product, alleged defects in the product labeling, and Warner-Lambert's allegedly wrongful conduct in securing FDA approval. Following the presentation of the evidence, the jurors were instructed under Oklahoma law, see R. 3821, Tr. at 3228:5-7, to consider theories of negligence, strict products liability based on defective design or labeling, and deceit. R. 3821, Tr. at 3230:15-3240:15. The jurors were further instructed that, if they returned a verdict for the plaintiffs,

[4] The last decision of this Court to address the application of due process limitations to punitive damage awards in a products liability case involving a defendant's undifferentiated conduct in marketing a federally regulated, nationally marked product was *Honda Motor Co. v. Oberg*, 512 U.S. 415 (1994), a case that pre-dated the refinement of the Court's analytical approach in *Gore* and *State Farm*.

they were also required to determine whether plaintiffs had established by clear and convincing evidence that "Warner-Lambert Company acted in a reckless disregard of the rights of others and/or acted intentionally and with malice towards others." R. 3821, Tr. at 3242:1-5.

The jury returned a verdict of $1.55 million in actual damages, and further found "by clear and convincing evidence that Warner-Lambert Company acted in reckless disregard of the rights of others" and "acted intentionally and with malice toward others," R. 3823, Tr. at 3385:6-15, triggering the punitive damages phase of the trial. Under Oklahoma law, the jury was permitted to award punitive damages of the magnitude affirmed below only if the jury (1) considered seven statutorily enumerated factors that bear on a defendant's level of culpability and financial condition; (2) found by "clear and convincing evidence that . . . defendant has acted intentionally and with malice towards others;" and (3) further determined that, in the circumstances presented, the appropriate measure of punitive damages was an amount "not to exceed . . . the increased financial benefit derived by the defendant . . . as a direct result of the conduct causing the injury to the plaintiff and other persons or entities." Okla. Stat. tit. 23, § 9.1(C) (2002). Neither the Oklahoma statute nor the trial court judge, however, imposed any geographical limitations on the jury's consideration of the foregoing criteria. Specifically, over Petitioners' objections, R. 3823, Tr. at 3387:25-3389:20, the trial judge refused to provide the jury with *any* guidance regarding the constitutional limitations on their ability to impose a financial penalty based on Petitioners alleged involvement in "misconduct" outside the State of Oklahoma, on the alleged "profitability of the misconduct," or on the "financial benefit derived by [Petitioners] . . . as a direct result of the conduct. . . ." Okla. Stat. tit. 23, §§ 9.1(A)(1)-(2), (C) (1) (c) (2002).

Instead, the trial court judge read the jurors excerpts of the Oklahoma statute *verbatim*, which included a general instruction that the jury should consider "the profitability of the misconduct

to the defendant," R. 3823, Tr. at 3402:1-2, and instructed them that, using "sound reason," they were permitted to consider and award punitive damages in an amount less than or equal to "the increased financial benefit derived by the defendant as a direct result of the conduct that caused injury to the plaintiff," and to "grant the plaintiff punitive damages in such sum as you reasonably believe will punish the defendant and be an example to others." R. 3823, Tr. at 3401:8-3402:23. Seizing upon this opening, Respondent's trial counsel made no effort to confine her presentation to the financial consequences of Petitioners' conduct in Oklahoma, but urged the jury to calculate Warner-Lambert's "financial benefit" based on the undifferentiated, worldwide revenue figures reflected in Petitioners' annual reports:

> If you find . . . that this company acted not just recklessly but with intent, then you may award either twice the actual damages you have already awarded, *or the increased financial benefit to this company from the drug Rezulin.* That is what the [Oklahoma] statute allows you, that's what the Court has instructed you. *You can now look at how much money they made, profit, profit, financial benefit from the drug Rezulin.*
>
> So if you look at the annual reports, you will see that they had Rezulin profit in '97, '98 and '99. And we know from what Dr. Maloney testified to that they were looking at a greater than 30 percent profit margin on this drug. . . .
>
> *So the profit, the financial profit . . . of this drug to this company over these three years is $600 million. That's the profit from what they did. The profit from Rezulin over the five weeks that Michael Wakefield took the drug. . . . in that five-week time period Warner-Lambert Parke-Davis makes $21 million in profit on the drug. . . .*
>
> *So when* you *look at the financial benefit, . . . just the profit is a range of $21 million, which is the first*

> *five weeks he's on it . . . all the way to $600 million, which is the three-year profit that this company made off this drug.* It's a little technical when you read the annual reports, but if you have any question as to the benefits, the increase in stock price, the increase in income, the net sales or how much they earned on Rezulin alone, go back and look at the annual reports. . . .

R. 3823, Tr. at 3409:17-3411:3 (emphases added).

It is difficult to overstate the due process concerns that pervade a trial process that permits a lay jury to impose punitive damages in a single tort case somewhere in the vast divide between no recovery and $600 million based on worldwide revenue figures. The trial court's refusal to impose any geographical limitation on the jury's deliberations at the punitive damages phase invalidated the $10 million punitive damages verdict, because notwithstanding that the jury's finding of compensatory liability was necessarily limited to a determination that Petitioners' conduct was wrongful solely under Oklahoma law, the jury's punitive damages calculation was permitted to roam worldwide. Whatever relevance Warner-Lambert's out-of-state acts may have had to determining (1) Warner-Lambert's liability for actual damages; or (2) plaintiffs' eligibility to recover punitive damages,[5] the introduction of such evidence should

[5] In *Gore*, this Court observed that, though it was "error for the jury to use the number of sales in other States as a multiplier in computing the amount of its punitive sanction," evidence of such sales "may be relevant to the determination of the degree of reprehensibility of the defendant's conduct." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 n.21 (1996). In light of the Court's subsequent observation in *State Farm* that "as a general rule, . . . a State [does not] have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction," 538 U.S. at 421, it is questionable whether the Court's observation in *Gore* retains any vitality. In any event, absent carefully drawn and enforced limiting instructions, it is clear that evidence of out-of-state acts may influence a jury's mathematical calculation at the punitive damages phase of the trial.

have been policed carefully to ensure that it was not misused to calculate the amount of the sanction to avoid expanding the regulatory impact of a punitive damages award beyond the State's inherent authority to regulate. *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 420-22 (2003). Here, it was plainly improper to permit the jury to consider Petitioners' sales of Rezulin® outside of Oklahoma in fixing the dollar amount of the punitive damages award.

In *Gore*, while reserving on the question whether there is any circumstance in which "one State may properly attempt to change a tortfeasor's *unlawful* conduct in another State," *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 573 n.20 (1996), this Court made clear that a State has no authority to base a state law punitive damages award on a tortfeasor's *lawful* conduct in another State:

> As the Alabama Supreme Court noted, neither the jury nor the trial court was presented with evidence that any of BMW's out-of-state conduct was unlawful. . . . The Alabama Supreme Court therefore properly eschewed reliance on BMW's out-of-state conduct, . . . and based its remitted award solely on conduct that occurred within Alabama. The award must be analyzed in the light of the same conduct, with consideration given only to the interests of Alabama consumers, rather than those of the entire Nation.

Id. at 573-74 (footnote and citations omitted). The Court reiterated and expanded upon this proposition in *State Farm*:

> A State cannot punish a defendant for conduct that may have been lawful where it occurred. . . . Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction. Any proper adjudication of conduct that occurred outside Utah to other persons would require their inclusion, and, to those parties, the Utah courts,

> in the usual case would need to apply the laws of their relevant jurisdiction.

538 U.S. at 421-22 (citations omitted). Thus, as *Gore* and *State Farm* recognize, implicit in a state-by-state, case-by-case approach to the adjudication of tort liability is the principle that the law of one State cannot be invoked to punish a defendant for the financial consequences of conduct that took place outside of the State.

The State of Oklahoma has no conceivable, "legitimate interest" in punishing conduct (let alone lawful conduct) that occurs beyond its borders, and may not "use the punitive damages deterrent as a means of imposing its regulatory policies on the entire Nation." *Gore*, 517 U.S. at 568, 585; *see id.* at 571 ("one State's power to impose burdens on the interstate market . . . is not only subordinate to the federal power over interstate commerce, . . . but is also constrained by the need to respect the interest of other States") (citations omitted); *State Farm*, 538 U.S. at 421 (noting that State laws cannot be permitted to operate beyond State boundaries "'without throwing down the constitutional barriers by which all the States are restricted within the orbits of their lawful authority and upon the preservation of which the Government under the Constitution depends'") (citation omitted). Here, irrespective of the evidence that was introduced at trial relevant to the FDA approval process for Rezulin®, there was no attempt to demonstrate (let alone to ask the jury to find) that Petitioners' conduct was *unlawful* in any State *other than Oklahoma*. Once the jury returned a verdict of compensatory damages under Oklahoma law, however, there was no effort to confine the broader financial implications of the jury's verdict to Petitioners' conduct *within Oklahoma*. Though Petitioners specifically raised these issues on appeal, Appellants' Brief in Chief at 26-28, *Wakefield v. Warner-Lambert Co.*, No. 99,086 (Okla. Nov. 7, 2003); Appellants' Reply Brief at 22-25, *Wakefield v. Warner-Lambert Co.*, No. 99,086 (Okla. Jan. 20, 2004), the Oklahoma Court of Civil Appeals brushed Petitioners' arguments aside with the conclusory and manifestly

erroneous observation that the punitive damages award did "no[t] attempt[] to sanction Manufacturing Defendants for conduct legal in other states." Pet. App. at 18.

The lower court's refusal to acknowledge the bright-line, geographical limitations that bound punitive damages awards in the wake of *Gore* and *State Farm* unfairly threatens product manufacturers in at least four ways. *First*, because plaintiffs outside of Oklahoma are not bound by its judgment, the lower court's approach creates a grave risk of excessive, multiple punishments for the same conduct causing the exact same harms.[6] It is fundamentally unfair to allow a plaintiff in an individual case to collect punitive damages for conduct that affects different parties in other states, while subsequent juries in other states remain free to impose punishment for the very same conduct. As this Court explained in the context of an *in rem* action in which the Commonwealth of Pennsylvania claimed entitlement to certain funds under its escheat statute, a property owner "is deprived of due process of law if he is compelled to relinquish it without assurance that he will not be held liable again in another jurisdiction or in a suit brought by a claimant who is not bound by the first judgment." *W. Union*

[6] Ironically, the pertinent provisions of the Oklahoma statute provide that "[t]he trial court shall reduce any award for punitive damages . . . by the amount it finds the defendant . . . has previously paid as a result of all punitive damage verdicts *entered in any court of this state* for the same conduct by the defendant." Okla. Stat. tit. 23, § 9.1(C)(1)(c) (2002) (emphasis added) (Pet. App. at 23-24). The court below failed to address Petitioners' argument that – consistent with these terms – the Oklahoma statute limits the permissible scope of the jury's consideration to the impact of a defendant's conduct *in Oklahoma*. Appellants' Brief in Chief at 27, *Wakefield v. Warner-Lambert Co.*, No. 99,086 (Okla. Nov. 7, 2003). Regardless of how the Oklahoma statute should be interpreted as a matter of State law, however, the set-off provision only protects Petitioners from duplicative punitive damage awards by other Oklahoma courts. It does not relieve Petitioners from the threat of punitive damage awards outside of Oklahoma that are based in whole or in part on the same worldwide financial figures that were provided to the Tulsa jury.

Co. v. Pennsylvania, 368 U.S. 71, 75 (1961). *See also Ex Parte Lange*, 85 U.S. (18 Wall.) 163, 168-69 (1873) (describing "the maxim" in civil cases "that no man shall be twice vexed for one and the same cause"). That, however, is precisely the situation when a jury in an individual case is permitted to impose punitive damages that are unrelated to the injury to the plaintiff on the theory that the defendant committed other bad acts against individuals who are not before the court. *See Roginsky v. Richardson-Merrell, Inc.*, 378 F.2d 832, 839-40 (2d Cir. 1967) (Friendly, J.) (describing multiple-punishment problem); *Juzwin v. Amtorg Trading Corp.*, 718 F. Supp. 1233, 1235-36 (D.N.J. 1989) ("multiple awards of punitive damages for a single course of conduct violate the fundamental fairness requirement of the Due Process Clause," but there is no effective, nationwide remedy absent "Supreme Court decision or national legislation"). *See also Allied-Signal, Inc. v. Director, Div. of Taxation*, 504 U.S. 768, 777-78 (1992) (State must apportion taxes to the share of the income fairly attributable to the taxpayers' business within the State.).

Though the legal prohibition against multiple civil punishments has deep roots, until recently the issue was largely academic. In *Roginsky* – one of the first decisions to highlight the "destructive synergism between traditional punitive damages doctrine and modern mass tort litigation" (John Calvin Jeffries, Jr., *A Comment on the Constitutionality of Punitive Damages*, 72 Va. L. Rev. 139, 141 (1986)) – Judge Friendly noted that punitive damages had their genesis in intentional torts, in which "usually there is but a single victim; a punitive recovery by him ends the matter, except for such additional liability as may be provided by the criminal law." *Roginsky*, 378 F.2d at 838. That paradigm, however, was completely eclipsed in the last half century by the advent of mass tort litigation. *See* Jeffries, *supra*, 72 Va. L. Rev. at 141-43. In the case of a nationally distributed product, "punitive damages may be repetitively invoked against a single course of conduct in unfair and potentially ruinous aggregation." *Id.* at 139; see *Roginsky*, 378 F.2d at 839.

Second, by permitting the jury to assess punitive damages based on out-of-state sales in the absence of any evidence that such sales were unlawful in the jurisdictions in which they occurred, the lower court failed to account for the fact that other juries (or courts or regulators) considering precisely the same conduct might conclude that Petitioners did nothing wrong or, at least, that the conduct did not warrant punishment.[7] Until it was voluntarily withdrawn from the market by Petitioners, Rezulin® was an FDA-approved drug that was widely used with beneficial results for diabetes patients. *E.g.*, R. 3797, Tr. at 1778:25-1779:10; R. 3798, Tr. at 1836:9-25, Tr. at 1882:5-19, Tr. at 1884:2-10. Because the judgment in an individual case brought against a manufacturer that distributes its products nationwide is not binding on anyone other than the plaintiff, however, the lower court's "punish for everything" approach unfairly invites the repeated assessment of overlapping "percentage of net profit" punishments with potentially devastating consequences divorced from any rational notion of deterrence.[8]

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[7] In opposition to Petitioners' appeal below, Respondent baldly asserted that Warner-Lambert's "misconduct was illegal in every state," Appellees' Brief in Response at 27, *Wakefield v. Warner-Lambert Co.*, No. 99,086 (Okla. Dec. 29, 2003), but Respondent offered no record support for this assertion because there is none.

[8] Further compounding the lower courts' error, a major feature of Respondent's case-in-chief at trial was that Warner-Lambert had committed a fraud on the FDA by withholding critical information during the regulatory approval process and that, as a consequence, Warner-Lambert had been permitted to market a drug that never should have received federal approval in the first place. *See, e.g.*, Pet. App. at 3; R. 3821, Tr. at 3269:10-3285:17. As this Court made clear in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001), however, "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." Even assuming that, post-*Buckman*, it is permissible for a plaintiff to introduce alleged evidence of fraud-on-the-FDA in support of state common law claims sounding generally in strict products liability and deceit, it is impossible to reconcile

(Cont'd)

Third, by abdicating its constitutional responsibility to impose appropriate limits on the jury's discretion, the lower court elevated the jury to the position of a *de facto* national regulator, passing judgment on, and doling out punishment for, the marketing of Rezulin® throughout the United States and beyond. Though our legal system long has recognized a lay jury's competence to decide specific factual issues relating to the claims of the parties before it, there is no basis for concluding that a lay jury has the expertise and resources to act as a super-regulator. In this case, the trial court's refusal to instruct the jury on the proper limitations of its role permitted the jury to impose fact-bound judgments rendered pursuant to Oklahoma law and the standards of the Tulsa community on Petitioners' conduct in the world at large. Simply put, the jury was permitted to sanction Petitioners for out-of-state sales in the absence of

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(Cont'd)

Respondent's reliance on *national sales* of an FDA-approved drug at the punitive damages phase of the trial with the reasoning of *Buckman*:

> State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants – burdens not contemplated by Congress in enacting the FDCA and the MDA. . . .
>
> [F]raud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs. . . .

Id. at 350, 351. Here, in the absence of proper limiting instructions, the jury effectively was permitted not only to consider Respondent's fraud-on-the-FDA theory under the rubric of Oklahoma law, but to punish Petitioners under Oklahoma law for "financial benefits" obtained on a nationwide (and, indeed, worldwide) basis.

any competent legal or evidentiary grounds for a reasoned judgment about the lawfulness or unlawfulness of Petitioners' conduct beyond Oklahoma's borders.

Fourth, the unfairness inherent in the lower court's approach is magnified by the burden that it imposes upon a corporate defendant in an individual tort case to defend not only against the underlying cause of action, but also against an amorphous "smear campaign" that seeks to penalize the defendant for the financial consequences of out-of-state conduct in the absence of any showing that the extraterritorial conduct was unlawful. Here, notwithstanding that the jury's finding of compensatory liability was based solely on the application of Oklahoma law, the jury was permitted to impose punitive damages on Petitioners based on sales of Rezulin® worldwide. This put Petitioners in an impossible position because, though it is a plaintiff's burden under Oklahoma law to prove a right to recover punitive damages by clear and convincing evidence, once the trial court allowed worldwide revenues into the equation there was no effective way that Petitioners could rebut Respondent's enormous, back-of-the-envelope punitive damages calculation. By forcing the corporate defendants into this position, the trial court tipped the litigation playing field dramatically and unjustifiably in plaintiffs' favor.

II. Certiorari Should Be Granted Because, Contrary To This Court's Precedents, The Lower Court Failed To Conduct Any Meaningful *De Novo* Review In Response To Petitioners' Arguments That The $10 Million Punitive Damages Award Was Excessive

In *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 436 (2001), this Court held that appellate courts must conduct a *de novo* review to ensure that a trial court's award of punitive damage comports with the three excessiveness guideposts laid down in *Gore*: degree of reprehensibility, ratio, and (where applicable) sanctions for comparable misconduct. *Gore*, 517 U.S. at 575-85. The Court reiterated that mandate in *State Farm*, observing that "[e]xacting appellate review ensures

that an award of punitive damages is based upon an application of law, rather than a decisionmaker's caprice." 538 U.S. at 418 (internal quotation marks and citation omitted). In neither *Cooper Industries* nor *State Farm*, however, did the Court instruct lower courts as to the precise meaning of "exacting" review in the context of determining whether the punishment is commensurate with the *Gore* factors.

In the instant case, from all that appears on the face of the decision below, the Oklahoma Court of Civil Appeals either misapprehended or ignored the gravamen of Petitioners' constitutional objections to the punitive damages award. On appeal, Petitioners argued at length, among other things, that (1) the trial court improperly permitted the punitive damages award to be based on out-of-state sales in the absence of any showing that such sales were unlawful; and (2) that the award was excessive. Appellants' Brief in Chief at 26-29; Appellants' Reply Brief at 22-29. On the first point, Petitioners argued that the jury should not have been permitted to "consider[] . . . conduct that did *not* cause any injury, such as Warner-Lambert's sales to people who benefitted greatly from Rezulin and experienced no ill effect," and that because the jury was permitted to rely on "*worldwide gross sales* of Rezulin as the measure of Warner-Lambert's increased financial benefit, the jury's punitive award violated the statutory and constitutional requirement that only the impact of the Defendant's conduct in *Oklahoma* may be considered in assessing punitive damages." Appellants' Brief in Chief at 26-27. On the second point, Petitioners argued that the punitive damages award was obviously excessive because it was based on revenue figures that had nothing to do with Oklahoma and disproportionate in its own right. *Id.* at 28-29.

In response to these arguments – and notwithstanding Respondent's concession that the jury was "presented . . . with a wide range of numbers to consider for punitive damages: $600 million in worldwide sales to $21 million [in worldwide sales] during just the five (5) weeks that Wakefield took

Rezulin," Appellees' Brief in Response at 27 – the court below offered nothing more than a conclusory and manifestly erroneous rebuttal:

> Manufacturing Defendants do not specifically elucidate how the result of this case violates either of these principles, and we find it does not. The punitive damages award in this case neither reflects a grossly excessive award, nor attempts to sanction Manufacturing Defendants for conduct legal in other states.

Pet. App. at 18.

The lower court's refusal to exercise any meaningful supervisory role over the jury's award resulted in a clear miscarriage of justice. *First*, an appellate court cannot simply rubber-stamp a punitive damages award in the absence of any discernible evidence that the award comports with constitutional norms. *See Honda Motor Co. v. Oberg*, 512 U.S. 415, 432 (1994) (rejecting arguments that jury instructions provided defendant with sufficient protection against arbitrary imposition of punitive damages, and holding that appellate review is "one of the few procedural safeguards which the common law provide[s] against that danger"). Here, though the jury could not possibly have reached the $10 million figure without considering the "increased financial benefit derived by the defendant" (R. 3823, Tr. at 3402:1-2, 15-20), the record was completely bereft of any evidence that would have permitted the jury to tie the $10 million to the "increased financial benefit" that Warner-Lambert derived in Oklahoma. Beyond concluding that the jury's award was necessarily based on some consideration of the "increased financial benefit" cap in the Oklahoma statute, any argument about the basis for the jury's calculation is purely speculative, because the figure might as well have been pulled out of thin air. *See Gore*, 517 U.S. at 593-94 (Breyer, J., concurring) ("[C]ourts properly tend to judge the rationality of judicial actions in terms of the reasons that were given, and the facts that were before the court, . . . not those that might have been

given on the basis of some conceivable set of facts. . . ."); *TXO Produc. Corp. v. Alliance Res. Corp.*, 509 U.S. 443, 486 (1993) (O'Connor, J., dissenting) ("[D]ue process does not simply require that a particular result be substantively acceptable; it also requires that it be reached on the basis of permissible considerations.").

Second, though this Court has not yet considered the question, the proportionality concerns voiced in *Gore* and *State Farm* are heightened where, as here, a case does not involve a particularized course of conduct directed specifically at the plaintiff, but a generalized course of conduct that resulted in the widespread distribution of a product in interstate commerce. In *State Farm*, the threat of duplicative punitive damage awards was sharply reduced by virtue of the fact that, at the core, plaintiffs' case was about State Farm's handling of an insurance claim on its unique facts. 538 U.S. at 412-15, 419. In this case, by contrast, the jury passed judgment under Oklahoma law on the lawfulness of Warner-Lambert's conduct in securing regulatory approval and marketing an FDA-approved drug. Warner-Lambert had no personal contact with the injured party or his representatives until suit was commenced, and Warner-Lambert's conduct vis-à-vis the injured party was indistinguishable from its conduct in designing and marketing the product nationally.

Without impugning a successful tort plaintiff's entitlement to recover compensatory damages, *amici* submit that the historical rationale for allowing punitive damage awards (let alone substantial awards) is largely if not entirely lacking in cases like the one at bar. Historically, punitive damages were typically reserved for cases involving intentional torts directed at a single victim. *Roginsky*, 378 F.2d at 838. Furthermore, because punitive damages are about deterrence and not compensation, they are intended to "serve the same purposes as criminal penalties," *State Farm*, 538 U.S. at 417, at least partly out of a concern that, if the defendant is not adequately punished with civil liability, its conduct will escape any other government

sanction. Where mass torts in the products liability field are concerned, however, these historical rationales collapse. As Judge Friendly observed:

> We have the gravest difficulty in perceiving how claims for punitive damages in such a multiplicity of actions throughout the nation can be so administered as to avoid overkill. . . . We know of no principle whereby the first punitive award exhausts all claims for punitive damages and would thus preclude future judgments. . . .
>
> * * *
>
> While jurisprudes might comprehend why Toole in California should walk off with $250,000 more than a compensatory recovery and Roginsky in the Southern District of New York and Mrs. Ostopowitz in Westchester County with $100,000, most laymen and some judges would have some difficulty in understanding why presumably equally worthy plaintiffs . . . elsewhere in the country should get less or none.
>
> * * *
>
> [I]f we were sitting as the highest court of New York we would wish to consider very seriously whether awarding punitive damages with respect to the negligent – even highly negligent – manufacturer and sale of a drug governed by federal food and drug requirements . . . and the present vigorous attitude toward enforcement, would not do more harm than good. A manufacturer distributing a drug to many thousands of users under government regulation scarcely requires this additional measure for manifesting social disapproval and assuring deterrence. Criminal penalties and heavy compensatory damages, recoverable under some circumstances even without proof of negligence, should sufficiently meet these

> objectives, and the other factors cited as justifying punitive damage awards are lacking.

Roginsky, 378 F.2d at 839-41. In cases that arise out of generalized, undifferentiated conduct that implicates the rights of private parties nationwide, whatever freedom a State court enjoys to invoke common law tort principles to regulate the conduct of corporate actors within the State's borders must be tempered by the recognition that the State court is not operating in a vacuum.

In such a case – and where, as here, "compensatory damages are substantial" – *amici* respectfully submit that a punitive damages ratio "equal to compensatory damages . . . can reach" – if not substantially exceed – "the outermost limit of the due process guarantee." *State Farm*, 538 U.S. at 425. This is particularly so because of the substantial direct and indirect burdens that the threat of unrestrained, repetitive punitive damage awards impose on interstate commerce. If individual State courts are permitted to impose enormous financial penalties on product manufacturers by punishing out-of-state conduct, the threat embedded in this unlawful form of extraterritorial regulation will burden manufacturers' activities nationwide. Furthermore, unless and until manufacturers of nationally distributed products are provided with additional safeguards against the runaway imposition of overlapping punitive damage awards, manufacturers will be discouraged from bringing beneficial products to market despite a federal regulatory environment that recognizes that the benefits associated with certain products outweigh the risks. The *ratio decidendi* reflected in the decision below is not only intellectually divorced from the traditional rationales that have been offered for the imposition of extraordinary sanctions, but threatens to substitute corporate destruction for corporate deterrence.

Third, *Gore* and *State Farm* teach that where compensatory damages are substantial (here, $1.55 million), punitive damages ordinarily should not exceed compensatory damages except in cases of highly reprehensible conduct. The *State Farm* Court emphasized the "long legislative history, dating back over 700 years and going

forward to today, providing for sanctions of double, treble, or quadruple damages" and indicated that, although such ratios "are not binding, they are instructive." 538 U.S. at 425. "When compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee," and ratios as high as 4 to 1 are "close to the line of constitutional impropriety." *Id.* Here, the lower court's affirmance of a 6.5 to 1 sanction should not be permitted to stand not only because the award was founded on constitutionally impermissible evidence of out-of-state revenue, but because the lower court failed to conduct any meaningful, *de novo* proportionality analysis. Even assuming that there were some evidentiary basis to support the Oklahoma jury's heavy imposition on a federally regulated and approved product (which there is not), *Gore* and *State Farm* plainly require that a reviewing court do more than the Oklahoma Court of Civil Appeals undertook to do in this case.

CONCLUSION

For all of the foregoing reasons and for the reasons set forth in the petition, the Court should grant the petition on the questions presented and reverse the decision of the Oklahoma Court of Civil Appeals.

Respectfully submitted,

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IN THE
Supreme Court of the United States

WARNER-LAMBERT CO., *et al.*,
Petitioners,

v.

MARY ROSE WAKEFIELD,
Respondent.

On Petition for a Writ of Certiorari to the Oklahoma Court of Civil Appeals

MOTION FOR LEAVE TO FILE AND BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

Pursuant to Rule 37.2 of the Rules of this Court, Pharmaceutical Research and Manufacturers of America (PhRMA) requests leave to file the accompanying brief as *amicus curiae* in support of Petitioners. Petitioners have consented to the filing of this brief. Counsel for Respondent Wakefield did not respond to multiple requests for consent.

PhRMA is a voluntary, nonprofit association that represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA member companies produce the vast majority of the prescription medicines used in the United States, and invested an estimated $38.8 billion in discovering and developing new medicines in 2004. This substantial private research effort is the source of virtually all new drugs marketed in the United States.

The issues presented are of fundamental importance to the pharmaceutical industry, because the imposition of massive punitive damages threatens particularly grave consequences for this industry, and for public health generally. Pharmaceuticals are approved by the Food and Drug Administration and marketed nationwide (and, as in this case, globally), so a rule that permits punitive damages to be imposed on the basis of global revenues for drug sales threatens to impose particularly heavy and unwarranted burdens on the pharmaceutical industry. This is all the more true because the discovery and development of new drugs is such an expensive, time-consuming and risky process. It takes up to 15 years, and close to 10,000 failures, for every one success in developing a new drug. Even then, only three out of every 10 medicines brought to market generate enough revenue to cover the average out-of-pocket costs of researching and developing a new medicine. The imposition of punitive damages like those at issue here, which are constitutionally excessive and have no nexus to the place of the alleged injury, threatens to stifle innovation in the pharmaceutical industry and to lessen the availability of pharmaceuticals, all to the detriment of public health.

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QUESTIONS PRESENTED

1. Whether a punitive damages award, which was based on worldwide gross sales of an FDA-approved prescription drug, conflicted with *State Farm Mutual Automobile Insurance Co.* v. *Campbell*, 538 U.S. 408, 422 (2003), and *BMW of North America, Inc.* v. *Gore*, 517 U.S. 559 (1996), which prohibit the imposition of punitive damages on the basis of lawful out-of-state conduct.

2. Whether a $10 million punitive damages award was grossly excessive under *State Farm* and *BMW*, given that compensatory damages were $1.55 million, and that under *State Farm*, where "compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee."

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INTEREST OF *AMICUS CURIAE*[1]

The interest of *amicus curiae* is set forth in the accompanying motion for leave to file this brief.

SUMMARY OF ARGUMENT

The court below permitted punitive damages to be awarded based on Warner-Lambert's *global* sales of a lawful, FDA-approved drug, despite the fact that Wakefield put on no evidence that Warner-Lambert made any illegal sale of the drug in *any* jurisdiction, foreign or domestic, outside of the forum State. The decision below directly contravenes this Court's holdings in *State Farm Mutual Automobile Insurance Co.* v. *Campbell*, 538 U.S. 408 (2003), and *BMW of North America, Inc.* v. *Gore*, 517 U.S. 559 (1996), concerning the unavailability of punitive damages for out-of-state conduct. Moreover, the award of $10 million in punitive damages, despite an already "substantial" compensatory award of $1.55 million, 538 U.S. at 425, is flatly incompatible with the Court's guidance about the proper ratio between punitive and compensatory damages.

The possibility of unconstitutionally excessive punitive damages awards against drug manufacturers threatens to discourage medical research and, in the absence of this Court's intervention, to inhibit Americans' access to significant and beneficial pharmaceutical therapies. Properly applied, the due process limitations on punitive damages awards elucidated in *BMW* and *State Farm* would prevent the imposition of standardless punitive damages that have long threatened the pharmaceutical industry.

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[1] Pursuant to Rule 37.6, PhRMA states that no counsel for a party authored this brief in whole or in part, and no person or entity, other than PhRMA or its members, made a monetary contribution to the preparation or submission of this brief. A list of PhRMA's members is available at http://www.phrma.org/whoweare/members.

Excessive punitive damages awards such as this one spawn grave consequences for public health. As PhRMA demonstrates in this brief, such excessive tort liability, as well as the fear of such liability, have discouraged research and development and have diminished the availability of beneficial products to those who need them. These adverse developments have impaired physicians' access to important and often unique pharmaceutical therapies, and have thereby interfered with doctors' ability to provide the highest quality medical care to their patients.

Punitive damages particularly compromise the development and distribution of new drugs. Pharmaceutical research and development are unusually expensive, time-consuming tasks. Despite extensive testing and exacting federal regulation, full knowledge of the risks presented by a new drug can never be gained before marketing. And all drugs are associated with adverse events in some patients. These harms cannot be avoided, regardless of the degree of care exercised by the manufacturer and the prescriber. FDA's goal, therefore, is not to eliminate all risk from new medicines; to do so would be counterproductive, harming public health by needlessly limiting public access to beneficial drugs. Rather, FDA's purpose is to ensure that these inevitable risks are appropriate in light of the expected benefits. When FDA has made such a determination, as it did here in approving Rezulin, the imposition of punitive damages at all—much less punitive damages of the unconstitutional magnitude awarded here—is unjustifiable. Under such circumstances, it is simply implausible to claim that a drug manufacturer has acted with malice such that punitive damages are appropriate. This Court should grant review to prevent the significant harm to public health that the decision below, and others like it, are likely to cause.

REASONS FOR GRANTING THE PETITION

I. THE DECISION BELOW SQUARELY CONFLICTS WITH *STATE FARM* AND *BMW*.

This Court's decisions in *State Farm* and *BMW* recognized clear due process limitations on the permissible bases for, and scope of, punitive damages awards. The decision below disregards those limits. Although the Petition ably sets forth this important conflict, the errors below cannot go unremarked here both because of their severity, and because these errors take on heightened importance in the pharmaceutical context, see *infra* Sections II, III.

1. First and foremost, in upholding a punitive damages award premised on not just *national*, but *international* sales of the FDA-approved drug Rezulin, the court below contravened *State Farm* and *BMW*. Both *State Farm* and *BMW* evaluated punitive damages awards based, at least in part, on lawful out-of-state conduct. And in both cases, this Court made clear that such conduct cannot form the basis of a punitive damages award:

> A State cannot punish a defendant for conduct that may have been lawful where it occurred. Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction.

State Farm, 538 U.S. at 421 (citations omitted); accord *BMW*, 517 U.S. at 572. Furthermore, it is rarely if ever appropriate for one State to punish even *un*lawful extraterritorial conduct. See, *e.g.*, *BMW*, 517 U.S. at 585 (a State may not "use the punitive damages deterrent as a means of imposing its regulatory policies on the entire Nation"); *Huntington* v. *Attrill*, 146 U.S. 657, 669 (1892) ("Laws have no force of themselves beyond the jurisdiction of the state which enacts them, and can have extraterritorial effect only by the comity of other states."). Even if a State could punish unlawful extraterrito-

rial conduct, the determination of unlawfulness must normally be based upon the laws of the foreign State. *State Farm*, 538 U.S. at 421-22.

The punitive damages award in this case is flatly inconsistent with the rule of *State Farm* and *BMW*. It rests on an Oklahoma statute permitting punitive damages to be awarded based on "the increased financial benefit derived by the defendant ... as a direct result of the conduct causing the injury to the plaintiff *and other persons or entities*," Okla. Stat. tit. 23, § 9.1(C)(2)(c) (emphasis added), regardless of the geographic location of those other people and regardless whether the conduct was lawful where it occurred.[2] Wakefield argued that "financial benefit" under this statute should be based upon the profit Warner-Lambert derived from worldwide sales of Rezulin during the period she took the drug. See Pet. 13. And that is what the court below understood to have been the basis for the punitive damages award. Pet. App. 16-17.

Thus, the punitive damages were predicated upon innumerable out-of-state actions involving countless out-of-state parties—namely, sales of Rezulin in States other than Oklahoma, and countries other than the United States. But at no point did Wakefield present evidence that Warner-Lambert's conduct in any such jurisdiction was unlawful. Wakefield did not even seek to apply the law of any other jurisdiction, as *State Farm* would require. 538 U.S. at 421-22.[3] And all of these

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[2] There are other provisions of Oklahoma law upon which the punitive damages award could theoretically have been based, *see generally* Okla. Stat. tit. 23, § 9.1, but none would justify an award of this magnitude. The court below took it as a given that subsection (C)(2)(c) was at issue. Pet. App. 16-17, 23.

[3] Nor would it be sufficient for Wakefield to claim that Warner-Lambert's conduct *might* have been unlawful in some other jurisdictions. Even leaving aside this Court's strong indication that unlawful out-of-state conduct is rarely if ever actionable, *State Farm*, 538 U.S. at 421; *BMW*, 517 U.S. at 585, *BMW* makes plain that a plaintiff seeking to impose punitive damages on this basis bears the burden of showing that the "out-of-state conduct was unlawful," 517 U.S. at 573. Indeed, Warner-Lambert's

errors were compounded by the use of Warner-Lambert's gross revenues, rather than merely its profits, in calculating punitive damages. Pet. 11. In short, *State Farm*'s requirements were unmet.

Not only did Wakefield fail to prove that these extraterritorial sales violated the law. In addition, she failed to present proof that would make the evidence of worldwide sales even *relevant*. *State Farm* held that "[l]awful out-of-state conduct may be probative," even when not directly relevant to a punitive damages calculation, "when it demonstrates the deliberateness and culpability of the defendant's action in the State where it is tortious." 538 U.S. at 422. But for proof to be used even for that limited purpose, the defendant's "conduct must have a nexus to the specific harm suffered by the plaintiff." *Id.* Here, there is no evidence at all demonstrating such a "nexus," nor could there be—there is no conceivable nexus between lawful, worldwide sales of Rezulin and the harm purportedly suffered by Wakefield. The court below erred, in direct contravention of this Court's precedents, in failing to require such proof.

Indeed, the refusal of the trial court to properly instruct the jury on this issue itself conflicts with *State Farm*. In *State Farm*, the Court held that "[a] jury *must* be instructed ... that it may not use evidence of out-of-state conduct to punish a defendant for action that was lawful in the jurisdiction where it occurred." 538 U.S. at 422 (emphasis added). Yet the trial court refused to instruct the jury that it could not punish the defendant for extraterritorial conduct. Indeed, it overruled objections on this same basis. Pet. App. 6, 16-17. This obvious mistake requires correction by the Court, lest other courts, in Oklahoma and elsewhere, follow this same approach.

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conduct almost certainly was lawful in certain other States—such as, for instance, Michigan, where FDA approval forecloses state-law tort liability. *See* Mich. Comp. Laws § 600.2946(5).

2. Certiorari is further warranted because the decision below disregards limits on the proper ratio between punitive and compensatory damages set forth in *State Farm* and *BMW*. Although the Court has said that there is no "bright-line ratio which a punitive damages award cannot exceed," *State Farm*, 538 U.S. at 425, it has also given the lower courts significant guidance about appropriate ratios. The Court has repeatedly indicated that a 4-to-1 ratio "might be close to the line of constitutional impropriety," *id.* (citing *Pacific Mut. Life Ins. Co.* v. *Haslip*, 499 U.S. 1, 23-24 (1991), and *BMW*, 517 U.S. at 581), and "referenced a long legislative history, dating back over 700 years and going forward to today, providing for sanctions of double, treble, or quadruple damages to deter and punish," *id.* Moreover, "[w]hen compensatory damages are substantial, then a ... ratio[] perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee." *Id.*

In *State Farm*, the award of $1 million was held to be "substantial." *Id.* at 426. The Court accordingly held that the *Gore* guideposts "likely would justify a punitive damages award at or near the amount of compensatory damages." *Id.* at 429. The award of $1.55 million in this case is, *a fortiori*, "substantial." The proper ratio is likewise "at or near the amount of compensatory damages." This conclusion is confirmed by the total lack of evidence of reprehensible conduct on the part of Warner-Lambert; on the contrary, all that the company did was to sell a drug—unquestionably beneficial to numerous users—that passed FDA's exacting approval process. See *infra* Section III. Yet the jury awarded punitive damages of $10 million. And instead of vacating the punitive damages award, or at least limiting punitive damages to comport with this Court's precedents, the court below upheld an award over *six times greater* than compensatory damages, without even attempting to justify this result.

The decision below is only the latest to disregard *State Farm* in this fashion. Every passing month brings additional

unconstitutional awards of punitive damages. On remand in *State Farm*, for instance, the Utah Supreme Court ignored this Court's statement that the punitive damages "'likely'" should be "'at or near the amount of compensatory damages'"—approximately $1 million. Instead, it awarded over $9 million in punitive damages. *Campbell* v. *State Farm Mut. Auto. Ins. Co.*, 98 P.3d 409, 410-12 (Utah), *cert. denied*, 125 S. Ct. 114 (2004). The Ninth Circuit likewise has disregarded *State Farm*. It has embraced the remarkable proposition that "*State Farm*'s 1:1 compensatory to punitive damages ratio is not binding, no matter how factually similar the cases may be." *Hangarter* v. *Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1014 (9th Cir. 2004). Other courts have similarly ignored *State Farm*.[4] The Court's review is needed to give force to its precedents.

II. EXCESSIVE PUNITIVE DAMAGES THREATEN PUBLIC HEALTH BY DECREASING INNOVATION AND THE AVAILABILITY OF PHARMACEUTICALS.

The disregard of *State Farm* set forth above and in the Petition takes on particular importance in the context of product liability suits concerning the marketing of pharmaceuticals. Mass tort actions against pharmaceutical manufacturers, in which massive punitive damages are sought, are by now

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[4] *E.g.*, *Eden Elec., Ltd.* v. *Amana Co.*, 370 F.3d 824, 828-29 (8th Cir. 2004) (upholding a punitive damages award of $10 million on the theory that that award was in fact "at or near" the compensatory damage award of $2.4 million), *cert. denied*, 73 U.S.L.W. 3363 (U.S. Feb. 22, 2005); *Rhone-Poulenc Agro, S.A.* v. *DeKalb Genetics Corp.*, 345 F.3d 1366, 1371-72 (Fed. Cir. 2003), *cert. denied*, 540 U.S. 1183 (2004) ($50 million punitive; $15 million compensatory); *Advocat, Inc.* v. *Sauer*, 111 S.W.3d 346, 361, 363 (Ark.), *cert. denied*, 540 U.S. 1004, 1012 (2003) ($21 million; $5 million); *In re the Exxon Valdez*, 296 F. Supp. 2d 1071, 1101, 1110 (D. Alaska 2004) ($4.5 billion; approximately $513 million "total actual harm"); *Interclaim Holdings Ltd.* v. *Ness, Motley, Loadholt, Richardson & Poole*, 298 F. Supp. 2d 746, 748, 765 (N.D. Ill. 2004) ($27.7 million; $8.3 million).

commonplace. Litigation against drug companies has been recognized as a growth industry for some time now. See Terence Dungworth, *Product Liability and the Business Sector* ix (RAND Inst. for Civil Justice 1988) ("no other defendants in any industry have experienced federal litigation growth comparable to that observed in asbestos or single-product pharmaceutical suits"). Over one 13-year period, approximately 11,000 such cases were brought in federal court alone. *Id.* at 38. That trend appears to have continued unabated. Merck, the manufacturer of the painkiller Vioxx, withdrew that product from the market only months ago. Seventy putative class actions have already been filed, in addition to hundreds of individual suits.[5] Wyeth (formerly American Home Products) has paid billions of dollars to litigate and settle claims stemming from voluntary withdrawal of the diet drug combination Fen-Phen—yet still faces lawsuits from more than *60,000* claimants who opted out of the settlement. See Melissa Nann Burke, *Philadelphia Sees 10,000 Fen-Phen Cases in 2004*, Nat'l L.J., Jan. 3, 2005, at 11.

Excessive tort verdicts in general, and punitive damages in particular, have wreaked havoc upon the federally regulated market for these products. Two effects of these suits deserve special mention, because they vividly illustrate the way the current liability environment is harming public health, and they demonstrate the need for this Court's intervention to reaffirm the constitutional limitations it has identified. *First*, such damages appear to stifle innovation in the pharmaceutical industry. Anticipated litigation costs have prevented drug

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[5] *See* Press Release, Merck, Merck Announces Voluntary Worldwide Withdrawal of VIOXX® (Sept. 30, 2004), *available at* http://www.merck.com/newsroom/press_releases/product/2004_0930.html; Susan Todd, *Vioxx Lawsuits To Be Rolled into One*, Newark Star-Ledger, Feb. 17, 2005, *available at* http://www.nj.com /business/ledger/index.ssf?/base/business-0/1108620648702 40.xml; Robert Steyer, *Vioxx Lawsuits Swamp Merck*, The Street.com, Dec. 14, 2004, *available at* http://www.thestreet.com/_googlen/stocks/robertsteyer/10199047.html?cm_ven=GOOGLEN&cm_cat=FREE&cm_ite=NA.

manufacturers from investing in new product development. Specific areas of research (such as vaccines) have been particularly affected. *Second*, excessive tort damages have reduced the availability of drugs. Not only are fewer drugs being researched and created—i.e., the "innovation" effect first noted—but also existing, FDA-approved, beneficial drugs have been removed from the market for fear of liability.

1. *Innovation.* The tort system is "having a profound negative impact on the development of new medical technologies." American Med. Ass'n, Report of the Board of Trustees, Impact of Product Liability on the Development of New Medical Technologies 1 (1988). "Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance." *Id.* As Justice O'Connor recognized some 15 years ago, "The threat of ... enormous [punitive damages] awards has a detrimental effect on the research and development of new products. Some manufacturers of prescription drugs, for example, have decided that it is better to avoid uncertain liability than to introduce a new pill or vaccine into the market." *Browning-Ferris Indus. of Vt., Inc.* v. *Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part).

This unfortunate effect may reflect a rational response to today's irrational liability environment, of which punitive damages are an important part. The choice to research and try to bring a new drug to market involves a calculation of expected benefits and expected costs. Massive tort verdicts can dramatically skew the cost side of that equation. Expenditures on research and development increase when liability costs decrease. See Amy Finkelstein, *Health Policy and Technological Change: Evidence from the Vaccine Industry* 22-24 (Nat'l Bureau of Econ. Research Working Paper No. 9460, 2003), *available at* http://www.nber.org/papers/

w9460.[6] And, where the level of risk is high—as it is in a system in which punitive damages have no reasonable bounds—the risk of liability is inversely related to investment in research and development activity. Michael J. Moore & W. Kip Viscusi, *Product Liability Entering the Twenty-first Century: The U.S. Perspective* 25, 27 (2001).[7]

Excessive liability—and, *a fortiori*, unbounded punitive damages awards of the sort blessed by the court below—has especially pernicious effects on vaccines, a particularly perverse effect in light of those products' unquestioned public health benefits. Am. Med. Ass'n, *supra*, at 6-7. The reason for this effect is simple: "Products with less market potential are more vulnerable to a given degree of liability potential." Steven Garber, *Product Liability and the Economics of Pharmaceuticals and Medical Devices* 167 (1993). And, where vaccines are concerned, "[t]he profit per dose is low,

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[6] Finkelstein's research focused on the Vaccine Injury Compensation Fund (VICF), a no-fault product liability system paid for by excise taxes on certain childhood vaccines. That system took the place of tort remedies stemming from those vaccines, and applied a fixed payment schedule for claims. *See* 42 U.S.C. §§ 300aa-10 to -34; 42 C.F.R. § 100.3. This alternative to the tort system had the salutary effects of reducing risk by normalizing payments and reducing expected liability costs. The result was stark—institution of the Fund led to a statistically significant increase in new clinical trials. Finkelstein, *supra*, at 22-24. Notably, plaintiffs' attorneys have attempted to circumvent the fixed-compensation regime of the VICF by bringing claims for injuries allegedly caused by thimerosal, a preservative used in certain vaccines, rather than by the vaccine itself. *See, e.g.*, *Moss* v. *Merck & Co.*, 381 F.3d 501 (5th Cir. 2004).

[7] *See also* W. Kip Viscusi & Michael J. Moore, *An Industrial Profile of the Links Between Product Liability and Innovation, in The Liability Maze: The Impact of Liability Law on Safety and Innovation* 81, 107, 114 (Peter W. Huber & Robert E. Litan eds., 1991); W. Kip Viscusi & Michael J. Moore, *Rationalizing the Relationship Between Product Liability and Innovation* ("*Rationalizing*"), *in Tort Law and the Public Interest: Competition, Innovation, and Consumer Welfare* 105, 123 (Peter H. Schuck ed., 1991). Viscusi and Moore's work considers the pharmaceutical sector among other industries, but does not focus exclusively upon it.

and yet the perceived liability per dose is high." John P. Wilson, *The Resolution of Legal Impediments to the Manufacture and Administration of an AIDS Vaccine*, 34 Santa Clara L. Rev. 495, 505 (1994); Viscusi & Moore, *Rationalizing*, at 111.

Thus, the Institute of Medicine has recognized that "apprehensions [about tort liability] act as a deterrent to vaccine production and thereby threaten the public's health." Inst. of Med., *Vaccine Supply and Innovation* 2 (1985); see also U.S. Congress, Office of Tech. Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards* 170, 182 (1993). Indeed, "[r]ising liability costs during the 1980s reduced the number of firms producing vaccines for five serious childhood diseases from thirteen in 1981 to three by the end of the decade." Viscusi & Moore, *Rationalizing*, at 111. Concerns about liability have slowed the progress of particular identifiable vaccines, including an AIDS vaccine. See Jon Cohen, *Is Liability Slowing AIDS Vaccines?*, Science, Apr. 10, 1992.[8]

The effect of liability on products with smaller market potential is a particularly timely issue. As science advances, there are greater opportunities for treatments tailored to particular types of individuals, such as patients with a particular genetic makeup, or who fail to respond to existing treatments. Although these treatments promise to be extremely beneficial, they may not generate markets large enough and predictable enough to offset the kinds of liability risks described above.

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[8] The development of contraceptives has similarly been slowed by liability concerns. Experiences like the forced withdrawal of Bendectin as the result of baseless tort suits (described *infra* at 12) have discouraged manufacturers from researching new products indicated for or associated with contraception and pregnancy. *See, e.g.*, Linda Johnson, *Wyeth Won't Resume Norplant Sales*, AP Online, July 26, 2002; Gina Kolata, *Will the Lawyers Kill Off Norplant?*, N.Y. Times, May 28, 1995; *see generally* Inst. of Med. & Nat'l Res. Council, *Developing New Contraceptives: Obstacles and Opportunities* 118-43 (Luigi Mastroianni, Jr. et al. eds., 1990).

2. *Availability*. In addition to discouraging initial product innovation, excessive liability adversely affects public access to beneficial pharmaceuticals by causing the discontinuation of clinical trials, and by forcing already-approved drugs and interested companies from the marketplace. See, *e.g.*, E. Patrick McGuire, The Impact of Product Liability 17 (The Conference Bd., Res. Rpt. No. 908, 1988) (quoting a drug manufacturer: "We have been forced to discontinue sale of therapeutically beneficial drugs because of excessive product liability costs.").

The signal example of market withdrawal concerns Bendectin, a drug approved by FDA for preventing nausea during pregnancy. Starting in 1969, assertions that Bendectin could produce birth defects began to appear in scientific literature. Yet no sound scientific study ever demonstrated a causal relationship between the drug and birth defects, and FDA continued to affirm its safety. Nevertheless, nearly 1700 lawsuits were brought against the manufacturer. Although the company won most cases, in 1983 it withdrew the drug in the United States because its $18 million in annual legal costs and insurance had nearly overtaken its $20 million in annual sales. Marvin E. Jaffe, *Regulation, Litigation, and Innovation in the Pharmaceutical Industry: An Equation for Safety, in Product Liability and Innovation: Managing Risk in an Uncertain Environment* 120, 126 (Janet R. Hunziker & Trevor O. Jonas eds., 1994). As a result, it was reported in 1994 that "treatment for severe nausea during pregnancy now accounts for nearly $40 million of the nation's annual hospital bill." *Id.* Yet "[i]t is unlikely that any new drug will be developed to close this therapeutic gap," *id.*—all this despite the fact that, as FDA reaffirmed in 1999, Bendectin was *not* withdrawn for safety reasons. See Determination That Bendectin Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 64 Fed. Reg. 43190 (Aug. 9, 1999).[9]

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[9] *See generally* Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development, in The Liability Maze: The Impact of Liabil-*

Given the vulnerability of vaccines to liability effects, see *supra* at 9-11 & n.6, it is no surprise that tort liability has diminished the availability of vaccines. Nearly all manufacturers of the diphtheria, pertussis, and tetanus (DTP) vaccine withdrew from the U.S. market due to lawsuits alleging harmful side effects filed in the 1980s. Lasagna, *supra*, at 341-45; see also *supra* at 10-11. In 1987, the CDC announced that the sole manufacturer of a vaccine to prevent Japanese encephalitis would no longer supply the product in the United States because of product liability concerns. Lasagna, *supra*, at 344. And commentators discussing the shortage and then surplus of flu vaccine this past winter have noted that there remain only two manufacturers licensed to sell the flu vaccine in the United States. *E.g.*, Anthony S. Fauci, *A Risky Business*, Wash. Times, Nov. 30, 2004, at A17 (column by the Director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health). In each of these ways, unbounded punitive damages harm public health, and for all of these reasons, the Court should grant the Petition.[10]

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ity Law on Safety and Innovation 334, 337-41 (Peter W. Huber & Robert E. Litan eds., 1991) (discussing the withdrawal of Bendectin).

[10] In addition, commentators have recognized that product liability, and liability concerns, have been reflected in higher prices. Some of this effect is direct—expected liability costs drive prices up. *See generally* Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & Econ. 203 (1997); Richard L. Manning, *Changing Rules in Tort Law and the Market for Childhood Vaccines*, 37 J.L. & Econ. 247, 258 (1994); Garber, *supra*, at 122; Gina Kolata, *Litigation Causes Huge Price Increase in Childhood Vaccines*, Science, June 13, 1986. There are also indirect effects that contribute to the same result. For instance, manufacturers are driven from the market, which leads to a lack of competition. W. Kip Viscusi, *The Social Costs of Punitive Damages Against Corporations in Environmental and Safety Torts*, 87 Geo. L.J. 285, 326 (1998). These price effects cause further harm to public health.

III. PUNITIVE DAMAGES ARE SINGULARLY INAPPROPRIATE IN LIGHT OF FDA'S STRICT SUPERINTENDENCE OVER PHARMACEUTICALS.

Finally, review is warranted because an award of punitive damages like this one is fundamentally incompatible with—and threatens to undermine—the comprehensive federal regulatory regime that governs new drug approvals. Punitive damages were awarded here on the theory that Warner-Lambert "acted intentionally and with malice toward others," Okla. Stat. tit. 23, § 9.1(C)(1), when it allegedly breached a claimed state-law duty to warn. The finding that Warner-Lambert acted with malice is implausible, given FDA's specific approval of precisely those warnings that formed the basis of the tort award. And the determination of malice is all the more inappropriate in light of the rigorous federal process of review for new drug approvals. That process includes FDA's scientific determination and legal approval of the specific warnings to be provided, and of their adequacy, and it constitutes FDA's conclusion that the drug may be marketed in interstate commerce. A finding of "malice" under such circumstances is gravely erroneous. An award of punitive damages reaching across state lines under such circumstances cries out for this Court's review.

1. The process of developing and obtaining approval to market a new drug is long and expensive. The process takes close to 15 years. Richard J. Findlay, *Originator Drug Development*, 54 Food & Drug L.J. 227, 227 (1999). By 2001, it was estimated to cost an average of $802 million per drug. Press Release, Tufts Ctr. for the Study of Drug Dev., Tufts Center for the Study of Drug Development Pegs Cost of a New Prescription Medicine at $802 Million (Nov. 30, 2001), *available at* http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6. The last phase of this process is regulatory approval. Under federal law, new drugs must obtain premarket approval from FDA to ensure that they are safe and effective, 21 U.S.C. §§ 355(d), 393(b)(2)(B), and not misbranded,

id. § 331(a), (b). FDA approval requires the submission of a New Drug Application, *id.* § 355(b), which includes reports on investigations for safety and efficacy, *id.* § 355(b)(1)(A), as well as "adequate tests ... to show whether or not [the] drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling," *id.* § 355(d), among other things.

The evaluation of a drug's safety and effectiveness under federal law is inextricably intertwined with its labeling. An applicant seeking approval of a new drug must submit proposed labeling to accompany the product. *Id.* § 355(b)(1)(F). FDA's regulations establish numerous and specific requirements for prescription drug product labeling, 21 C.F.R. pt. 201—including warnings that must reflect known risks based on reliable scientific evidence, *e.g.*, 21 C.F.R. § 201.57(e). The applicant may not deviate from FDA-approved product labeling without receiving supplemental agency approval. *Id.* § 314.70. False or misleading labeling constitutes misbranding, which is prohibited, 21 U.S.C. § 331(a), (b), and is subject to both criminal penalties and civil sanctions, *e.g.*, *id.* §§ 332, 333(a), 334(a).

FDA approved Rezulin, as well as every aspect of its labeling. The drug made its way through the extensive, exhaustive review process mandated by the Federal Food, Drug and Cosmetic Act (FDCA) and by FDA's implementing regulations. FDA determined that Rezulin's labeling was appropriate, and that it contained all necessary warnings. This determination flatly forecloses the claim that Warner-Lambert "acted intentionally and with malice toward others." Okla. Stat. tit. 23, § 9.1(C)(1). Under these circumstances, Warner-Lambert's conduct cannot have been sufficiently wanton to merit punitive damages at all, much less punitive damages of the unconstitutional magnitude awarded here. See *Roginsky* v. *Richardson-Merrell, Inc.*, 378 F.2d 832, 840-41 (2d Cir. 1967) (Friendly, J.) ("A manufacturer distributing a drug to many thousands of users under government regulation

scarcely requires [punitive damages] for manifesting social disapproval and assuring deterrence.").[11]

2. The award of punitive damages under these circumstances appears to be premised on the belief that drugs marketed to consumers can be free of harmful effects. This notion fundamentally misunderstands the nature of pharmaceuticals as well as the FDA approval process. The FDA long has recognized that "[t]here is no such thing as absolute safety in drugs. There are some drugs that are less liable to cause harmful reaction than others, but people die every year from drugs generally regarded as innocuous." Hearings on Drug Safety Before the Subcomm. on Intergovernmental Relations of the House Comm. on Gov't Operations, 88th Cong., pt. 1, at 147 (1964) (testimony of former FDA Commissioner Larrick); see also *Restatement (Second) of Torts* § 402A cmt. k (1965) (recognizing that many drugs are often "unavoidably

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[11] It is no answer to argue, as Wakefield surely will do, that punitive damages are appropriate because (as the court below described the allegation) defendants "downplayed and understated the dangers of the drug in order to obtain approval of the drug by the regulatory [FDA]." Pet. App. 3 (emphasis omitted). This Court has held that "fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law," precisely because "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration." *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); *id.* at 353 (Stevens, J., concurring).

Nor is it significant that a manufacturer may as a theoretical matter strengthen warnings without seeking FDA's prior approval. 21 C.F.R. § 314.70(c). Manufacturers rarely if ever make any such a change to drug labeling without FDA approval, because if a manufacturer does so and the FDA disagrees with the change, the manufacturer is in violation of the statutory provisions against marketing an unapproved new drug or a misbranded drug. 21 U.S.C. §§ 352, 355(a); *see* Richard M. Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 Food Drug Cosm. L.J. 233, 236 (1986) ("In actual practice, section 314.70(c) is rarely invoked."). Given that reality, a manufacturer's failure to amend FDA-compliant product labeling to comply with state law cannot be deemed sufficiently wanton to justify punitive damages.

unsafe," even "for their intended and ordinary use") (emphasis omitted).

The FDA approval process cannot, and does not, require that drugs be risk-free: "If the FDA were to demand absolute proof that no short-term or long-term health risks exist, no drug ever would reach the market." Steven R. Salbu, *The FDA and Public Access to New Drugs: Appropriate Levels of Scrutiny in the Wake of HIV, AIDS, and the Diet Drug Debacle*, 79 B.U. L. Rev. 93, 147 (1999). It would be impossible to implement a drug approval process that sought to prevent all adverse reactions, and costly beyond measure to do so. FDA categorizes an adverse reaction as "rare[]" if it occurs in 1 in 1000 cases. 21 C.F.R. § 201.57(g)(2). Yet even studies comprising 3000 patients are unable to identify "uncommon side effects, delayed effects, or consequences of long-term drug administration." Am. Med. Ass'n, *Reporting Adverse Drug and Medical Device Events: Report of the AMA's Council on Ethical and Judicial Affairs*, 49 Food & Drug L.J. 359, 359-60 (1994). Indeed, "to detect the difference between an adverse reaction incidence rate of 1/5000 and 1/10,000, approximately 306,000 patients would have to be observed, which is far more than any study could achieve." *Id.* at 360 (footnote omitted). And to insist upon no adverse reactions as a result of the drug would cause immeasurable harm to public health: "To take the drastic step of forbidding marketing of a drug until all long-term consequences and interactions are identified through formal research would impose unacceptable costs in the form of untreated or inadequately treated illness." *Id.*[12]

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[12] *Accord Vaccine Supply and Innovation*, *supra*, at 8 ("[T]here is no way totally to avoid injuries caused by current vaccines manufactured according to approved procedures and administered in accordance with recommended medical practices short of the total suspension of vaccine use, which is unacceptable because of the increased risk of morbidity and mortality.").

In short, FDA fully contemplates that the drugs it approves will carry some risk. "[S]afety does not mean zero risk." FDA, Report to the FDA Commissioner from the Task Force on Risk Management, Managing the Risks from Medical Product Use 3 (1999), *available at* http://www.fda.gov/oc/tfrm/riskmanagement.pdf. FDA has long acknowledged that its role is to conduct a risk-benefit analysis to determine what risk is *reasonable*. See *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979) ("the Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use"); FDA, Managing the Risks from Medical Product Use, *supra*, at 3 ("A safe product is one that has reasonable risks, given the magnitude of the benefit expected and the alternatives available."). As a former Chief Counsel to FDA has explained it, FDA "weighs the drug's therapeutic benefits against the potential risks of its use.... In short, the FDA effectively determines what risks physicians should be permitted to impose upon the patients they treat with therapeutic drugs." Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1, 9 (1973) (footnote omitted).

This comprehensive regulatory regime is incompatible with multimillion-dollar punitive damages awards, and it certainly forecloses the conclusion that a manufacturer whose drug has been approved pursuant to this process has acted with "malice." When FDA approves a drug, it has exercised its judgment by "weigh[ing] a variety of complicated information and tak[ing] into account a number of ... considerations." FDA, Managing the Risks from Medical Product Use, *supra*, at 30. That the agency has exercised its statutory and regulatory mandate is reason enough for state courts to be precluded from second-guessing the agency's decision. Cf. Administrative Procedure Act, 5 U.S.C. § 706(2)(A); *Chevron U.S.A., Inc.* v. *NRDC, Inc.*, 467 U.S. 837 (1984). Warner-Lambert was and is bound by the warning requirements contained in labeling approved by FDA via this regulatory process. Ac-

cordingly, it is simply impossible to conclude that Warner-Lambert acted "intentionally and with malice" by failing to provide additional warnings. To permit state courts to subject Warner-Lambert to punitive damages under such circumstances—much less punitive damages that are squarely foreclosed by this Court's precedents and by constitutional limits—undermines Congress's regulatory scheme, thwarts FDA's authority, and renders every State a mini-regulator of pharmaceuticals. The FDCA and the Constitution foreclose this result.

CONCLUSION

For the foregoing reasons, and those set forth in the Petition, the Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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